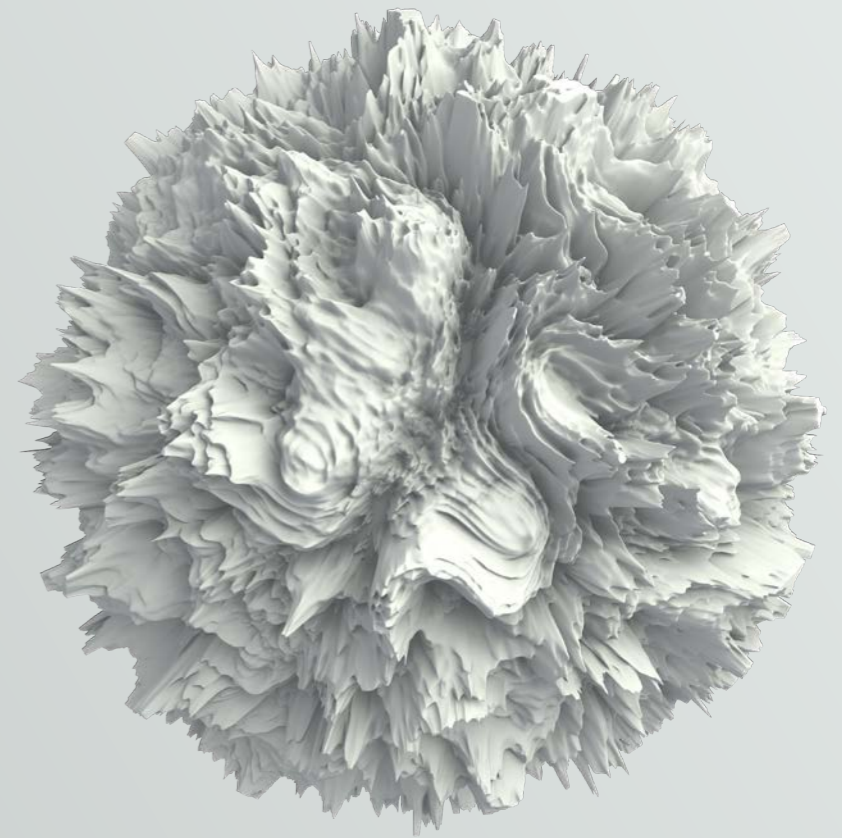
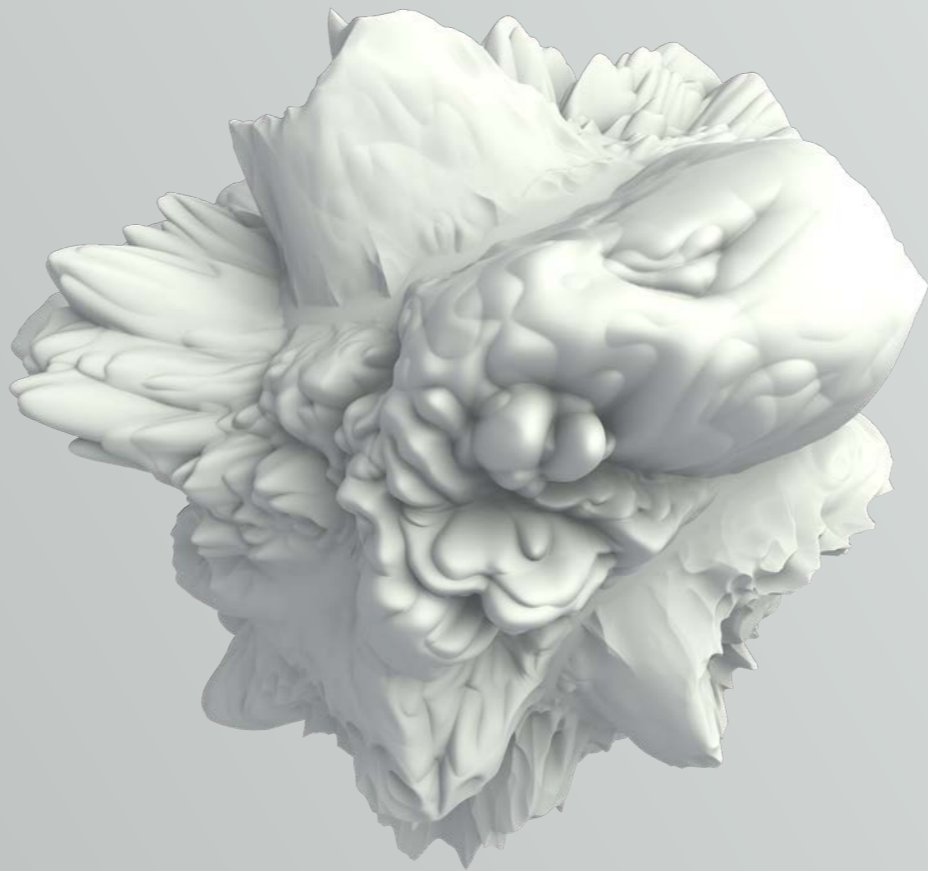


Drugs to Watch 2021





A medical moonshot in vaccines and strides against serious diseases



Despite the many challenges of 2020, drug development triumphed.

Through all the disruption, biopharmas managed to produce a crop of highly-effective vaccines and treatments that, scarcely a year into the pandemic, promise to downgrade a deadly disease to something more like a seasonal flu. It's the medical equivalent of many simultaneous moonshots, with dozens of SARS-CoV-2 vaccines in the pipeline yet.

Beyond the unprecedented achievements of the industry's response to COVID-19, drug developers have advanced milestone treatments for conditions affecting tens of millions of patients worldwide, including Alzheimer's and congestive heart failure. Among the new drugs and biologics that have either won approval or are on the cusp of doing so, we have identified four treatments that are likely to reach blockbuster status, delivering annual sales of more than \$1 billion within five years. These Drugs to Watch™ include:

- **Biogen and Eisai's aducanumab**, a potential game changer in the costly and so-far fruitless fight to build a pharmacopeia against Alzheimer's disease, which affects an estimated 50 million patients worldwide (not to mention their families and caregivers);
- **UCB's bimekizumab**, which promises significantly fewer side effects to patients with psoriasis, a condition affecting an estimated 2–3% of the global population, and potentially a host of other autoimmune diseases;
- **Takeda's relugolix**, one of the first of a new class of treatments, with an oral formulation to address prostate cancer, the second-most-common malignancy afflicting men, as well as endometriosis and uterine fibroids, painful conditions affecting millions of women;
- **Bayer and Merck's vericiguat**, an innovative heart failure treatment and the first indicated specifically for high-risk, chronic heart failure with reduced ejection fraction (HFrEF), a particularly at-risk population.

This year's list is a conservative one, reflecting, in part, a trend towards specialty drugs launching with very narrow initial indications and expanding gradually into others, over many years. This trend is particularly true for oncology therapeutics, where a still-relatively-young field of immuno-oncology agents (e.g., Keytruda, Opdivo, Yervoy) continues to expand its applications.

Other experimental treatments on our radar this year, ones which didn't quite fit our criteria for inclusion in this list, but which have notable potential, include: CAR T-cell immunotherapies from Bristol Myers Squibb (idecabtagenevicleucel) and Janssen (ciltacabtageneautoleucel), currently in FDA review for use in treating various multiple myeloma indications; Reata's bardoxolone methyl, an anti-inflammatory granted FDA Orphan Drug designation for treatment of connective tissue disease-associated pulmonary arterial hypertension and chronic kidney disease in patients with Alport syndrome; Pfizer and Lilly's tanezumab, an NGF inhibitor filed with FDA for treatment of chronic pain in moderate-to-severe osteoarthritis patients; LEO Pharma's tralokinumab and Galderma's nemolizumab, monoclonal antibodies for treatment of atopic dermatitis; and Pfizer's PF-06482077 experimental pneumonia vaccine.

In addition to rewarding shareholders and funding future innovation, these treatments hold enormous potential to advance human health, redefining standards of care in their categories and saving or improving patient lives. This report offers an overview of each of these four Drugs to Watch in 2021, along with a snapshot of the fast-emerging field of COVID-19 vaccines.



Contents

04 **Methodology**

05 **Data sources
and contributors**

06 **Drugs to Watch**

06 — Aducanumab

09 — Bimekizumab

12 — Relugolix

16 — Vericiguat

19 **COVID-19 vaccine
landscape**

24 **Looking ahead**

Methodology

Drugs to Watch showcases drugs entering the market that year with the potential to become blockbusters within five years. Blockbuster is defined by the common \$1 billion annual sales milestone.

Data and analysis to identify this year's Drugs to Watch drew from Clarivate life sciences solutions and integrated data sets that span the R&D and commercialization lifecycle.

Drug selection criteria:

- Drugs in phase 2 or phase 3 trials, at pre-registration or registration stage, or already launched early in 2021 were selected for analysis, including drugs launched for a new indication that could be particularly impactful on the industry; drugs launched prior to 2021 were excluded
- Dataset was then filtered for drugs that had total forecast sales of \$1 billion or more in 2025

Our experts then manually evaluated each drug in its individual context, based on factors such as expected approval or launch dates, competitive landscape, regulatory status, trial results, market dynamics and other factors.

From there, we determined four Drugs to Watch in 2021:

- **Aducanumab**
- **Bimekizumab**
- **Relugolix (Orgovyx)**
- **Vericiguat (Verquvo)**

The drug snapshots within the report draw from: interviews with therapy experts for the respective drug markets; Clarivate drug, disease landscape and forecast reports; Cortellis™ sales data (sourced from Refinitiv I/B/E/S); and other industry sources including biopharma company press releases and peer-reviewed publications.

This year's Drugs to Watch also includes a special section on the COVID-19 vaccine landscape, which summarizes the vaccines that were granted emergency use authorizations/conditional approvals as of February 10, 2021.

Please note that Clarivate analysts generated the data shown in this report on January 21, 2021 and the data were correct as of that time.



Data sources and contributors

Since 2013, Clarivate has applied the proprietary technologies, tools and techniques trusted by its global life sciences customers to produce the Drugs to Watch report.

Cortellis Competitive Intelligence™

provides access to data such as drug pipeline, deals, patents, global conferences and company content, along with the latest industry news and press releases.

Disease Landscape & Forecast

provides comprehensive market intelligence and actionable insights across 180+ indications to help optimize long-term disease strategies.

Drug Timeline & Success Rates

is an analytic tool that applies statistical modeling and machine learning to reliably and accurately forecast drug development milestones, timelines and probability of success.

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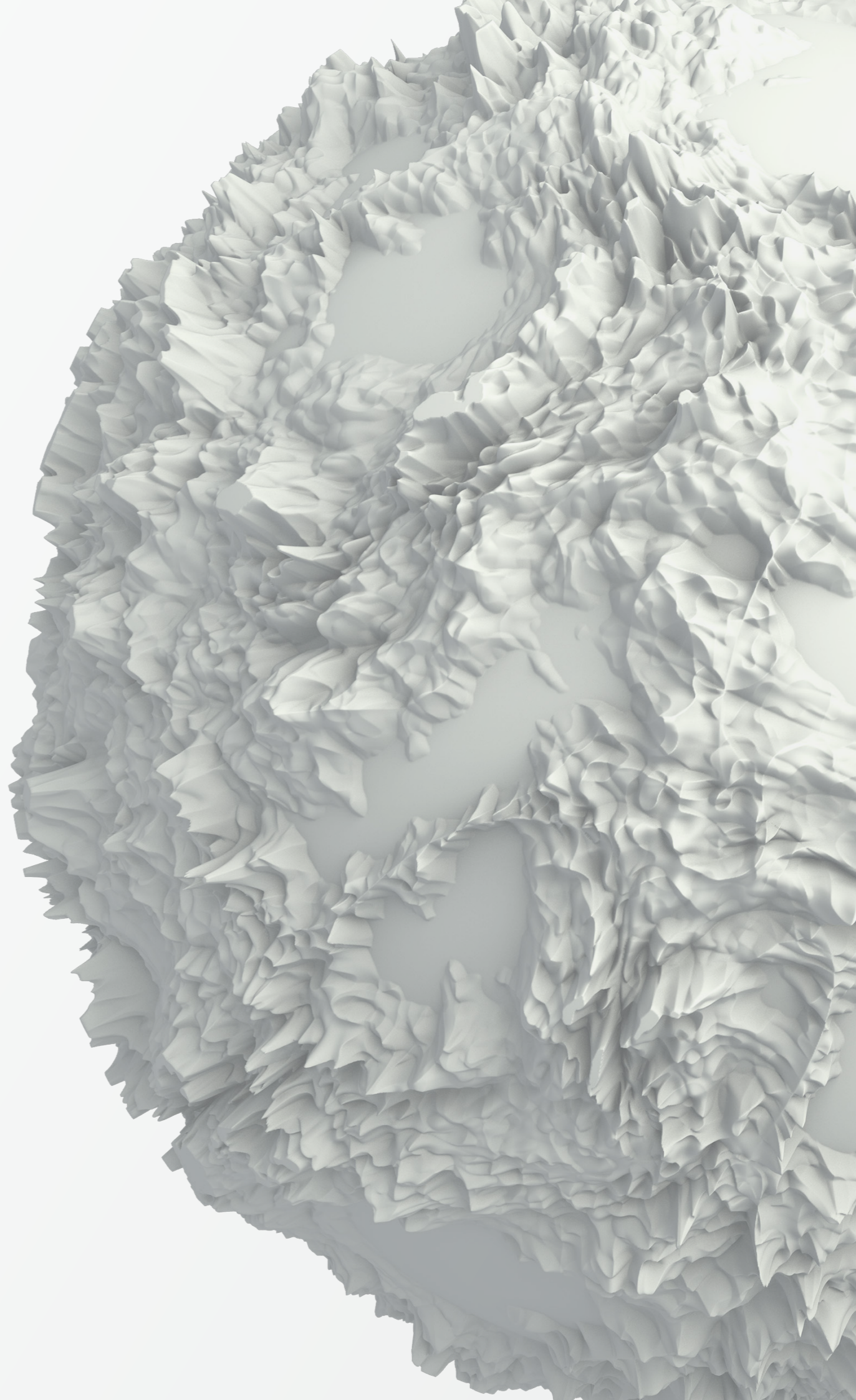
Prostate Cancer

Alice Zeng

Vaccines

Gang Wang

Chief Scientist,
Life Sciences, China



All eyes are on aducanumab, which could become the first disease-modifying therapy (DMT) for Alzheimer's disease (AD), a landmark achievement following decades of failure in this perennially underserved market.

About aducanumab

- Developed by Biogen Inc and Eisai Co Ltd
- Recombinant chimeric human IgG1 mAb targeting beta-amyloid
- In November 2020, FDA Advisory Committee issued a negative review, finding that available clinical trial evidence did not prove effectiveness
- After submission of additional data and analysis, PDUFA date was extended by three months to June 7, 2021 (as of Jan 29, 2021)
- Undergoing standard MAA/NDA review by the EMA and PMDA

Aducanumab

Aducanumab (BIIB037)
Neurology/psychiatric –
Alzheimer's disease

Market overview

~50m

people with Alzheimer's
disease globally

>30%

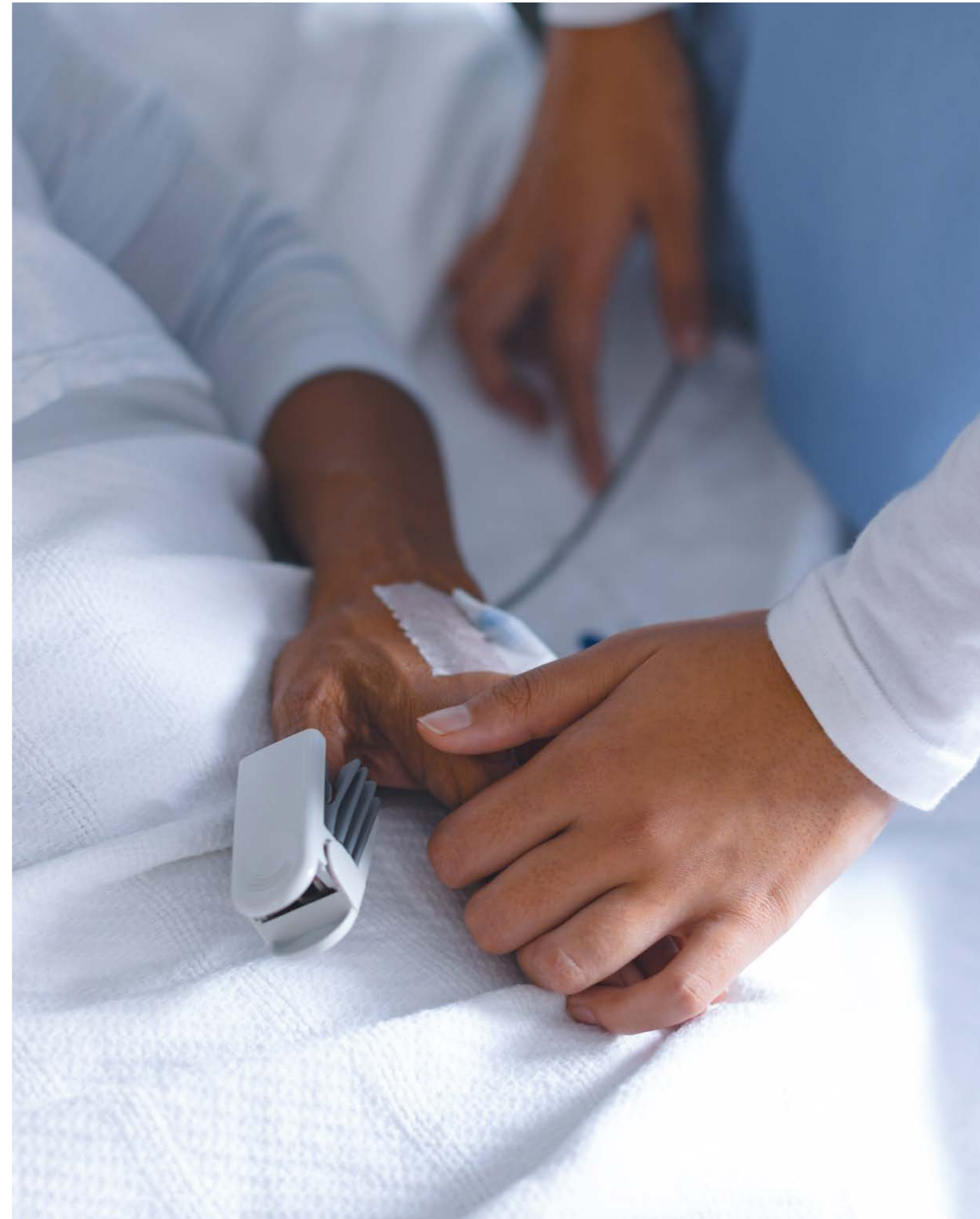
expected increase in total
prevalent cases of early
Alzheimer's disease by 2029
due to aging population

About the Alzheimer's disease market

- Currently only symptomatic therapy: AChEIs and memantine, now generic, are the standard of care across mild, moderate and severe disease
- No novel therapies approved in >15 years
- Other key anti-beta-amyloid DMTs in late-phase development: lecanemab (BAN2401; Eisai/Biogen) and gantenerumab (Roche)
- Many more drugs from a range of MOAs (e.g., tau-based therapies, sigma-1 receptor inhibitors and SIGLEC3 and Trem2 antibodies) are in mid- and late-phase trials

Unmet patient needs

The most critical need for patients has been a safe, effective DMT that slows cognitive decline. Tools that enable earliest possible diagnosis are also critical.



Aducanumab (BIIB037)
Neurology/psychiatric –
Alzheimer’s disease

Analysis

Why is it a drug to watch?

Aducanumab is the first putative DMT to demonstrate a clinical effect in early Alzheimer's disease patients in a phase 3 study and the first to undergo regulatory review. Results from the terminated ENGAGE/EMERGE and completed PRIME trials indicate that aducanumab is biologically active and suggest the potential for efficacy with sufficient exposure to the 10 mg/kg dose. If approved, it would mark a major clinical, commercial and regulatory milestone. However, the overall data package is complex and contentious given the limitations associated with the data and its analysis.

What to watch

The uncertainty around approval is the key factor. If approved, market access hurdles (cost/reimbursement and practical/logistical) will be the key rate-limiting factors.

What you need to know

Aducanumab could unlock a monumental opportunity to radically change AD patient care and transform the market. If approved, demand for treatment will be enormous, potentially even decreasing willingness to forgo this treatment for an investigational drug in future clinical trials. It could have a similar effect on companies' decisions about which drugs to develop, bypassing other sorely needed MOAs to develop next-gen anti-amyloid drugs. Nevertheless, many questions remain about the drug’s prospects, including, first and foremost, the probability of approval given the questions about its true efficacy, followed by future competition from other DMTs and overall health system preparedness—availability, cost and reimbursement of the drug and requisite diagnostic testing; patient/physician awareness to drive early presentation, specialist referral and diagnosis; and infusion infrastructure.

\$3.74B
expected sales in 2025

"I have to say that the data are convincing...there is clear clinical effect. I don’t think it’s a false positive. ...aducanumab is, biomarker-wise, the strongest thing possible... from the point of MOA, biomarkers and the effect on the brain amyloid and tau... for how long would you treat patients and what their dosage would be to achieve the clinical effects? If you look closely, the limited data they have sort of parallels the observations they made during phase 1."

Neurologist,
United States

Based on Cortellis data, there is a 49% probability of success for aducanumab in the U.S.



Source: Cortellis Competitive Intelligence, Drug Timeline & Success Rates
Prediction current as of January 26, 2021

Bimekizumab



This innovative psoriasis treatment promises substantially fewer side effects, along with modest gains in efficacy.

About bimekizumab

- Humanized monoclonal IgG1 antibody developed by UCB
- First biologic agent to enter phase 3 studies that simultaneously targets both IL-17A and IL-17F
- Undergoing review by the FDA and EMA as of September 2020 to treat moderate to severe, chronic plaque psoriasis based on data from three phase 3 trials showing superiority to placebo, ustekinumab (Stelara) and adalimumab (Humira)

Bimekizumab
UCB-4940; BKZ
Excessive immune response/
autoimmunity – psoriasis

Market overview

2–3%

estimated global
prevalence of psoriasis

About the psoriasis market

- Currently very crowded, with both biologic and non-biologic treatment options
- Biologic classes for psoriasis with the largest market share: TNF-inhibitors (typically first-line treatment; Humira, Embrel), IL-12/IL-23 (Stelara), IL-17 (Cosentyx, Taltz) and IL-23 (Tremfya, Skyrizi)
- Current mainstay: methotexate (non-biologic)
- Future market share likely to grow due to increasing evidence for IL-23 and IL-17 efficacy and physician familiarity with these drugs

Unmet patient needs

Current biologic treatments offer many patients relief, but often do not induce long-term remission. For a more comprehensive set of treatment options, patients would benefit from novel, efficacious, topical therapies without steroidal side effects and oral therapies that are safe and have an efficacy similar to that of biologics.



Bimekizumab
UCB-4940; BKZ
Excessive immune response/
autoimmunity – psoriasis

Analysis

Why is it a drug to watch?

While bimekizumab is a late-class entrant providing incremental improvement over existing treatment options, it is expected to have best-in-class efficacy and fewer serious side effects. Its dual inhibition of IL-17A and IL-17F differentiates its MOA from other biologics, and clinical trials results are promising. It also has the potential to benefit the ~30% of patients with concomitant psoriatic arthritis.

What you need to know

- Bimekizumab will likely be used as a third- or fourth-line treatment for patients with primary non-response, loss of response or unacceptable side effects with other treatments
- Long-term efficacy and safety profile will be crucial to the use of bimekizumab

Development also underway for:

- Psoriatic arthritis (PsA)
- Ankylosing spondylitis (AS)
- Non-radiographic axial spondyloarthritis (nr-axSpA)
- Ulcerative colitis
- Hidradenitis suppurativa

What to watch

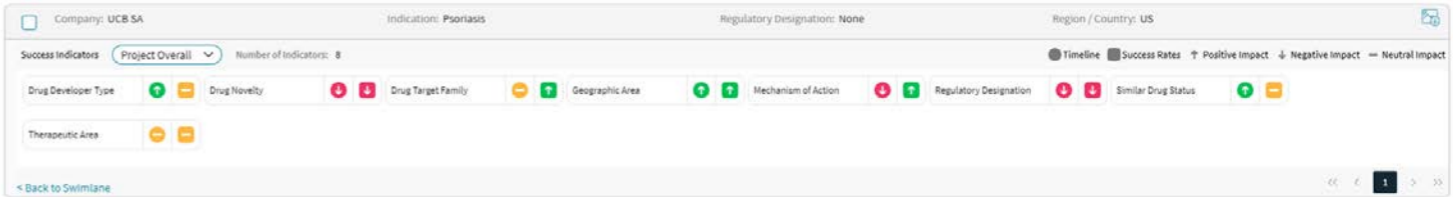
Bimekizumab's blockbuster status could be impacted by uptake of the IL-23 inhibitor SKYRIZI (risankizumab) and its anticipated approval for extension to PsA treatment in the U.S. and E.U. Also facing stiff competition within the IL-17 class, bimekizumab will need to achieve preferred inhibitor status on at least some of the three in-class competitors (brodalumab [Siliq], ixekizumab [Taltz] and secukinumab [Cosentyx]).

\$1.86B
expected sales in 2025

"It is highly likely to get approval. It is probably going to prove to be one of the fastest biologics we have and one of the most effective, but also it seems to be particularly effective for joint disease."

Dermatologist,
France

Based on Cortellis data, bimekizumab is predicted to reach first approval in the U.S.



Source: Cortellis Competitive Intelligence, Drug Timeline & Success Rates
Prediction current as of January 26, 2021

Relugolix



For these patients who have few effective treatment options, there is great opportunity for novel drugs to have a big impact on outcomes and quality of life. With relugolix, patients have an effective, oral choice, although with long-term hypoestrogenic side effects that will need to be taken into consideration and potentially managed.

About relugolix

- Developed by Takeda Pharmaceutical Co Ltd and licensees Myovant Sciences Ltd, Pfizer Inc, ASKA Pharmaceutical Co Ltd and Gedeon Richter
- GnRH receptor antagonist

Relugolix for prostate cancer

- Approved for treatment of prostate cancer in the U.S. (December 2020)
- Multicountry phase 3 (HERO) trial ongoing in Australia, Brazil, Canada, Europe, Japan, Mainland China, New Zealand, South Korea and Taiwan

Relugolix for endometriosis

- Phase 3 trials ongoing in Australia, Canada, Japan, New Zealand, South Africa, South America and the United States

Relugolix for uterine fibroids

- Approved for treatment of uterine fibroids in Japan (February 2019)
- Undergoing MAA/NDA review by the EMA and U.S. FDA
- Phase 3 trials ongoing in Brazil, Chile and South Africa

Relugolix
TAK-385; Orgovyx; Relumina
Oncology – prostate cancer
Reproductive health –
endometriosis & uterine fibroids

Market overview

1.5% CAGR

of diagnosed incident cases from 2019 to 2029, driving an increase in drug-treatable cases

2nd

most frequent malignancy in men worldwide

Oncology – prostate cancer

About the prostate cancer market

- Mainstay frontline treatment: androgendeprivation therapy, including orchidectomy, GnRH agonists and GnRH antagonists (administered alone or in combination with chemotherapy, radiotherapy or androgen antagonists)
- Primary competitors: Lupron depot (GnRH agonist), Firmagon (GnRH antagonist)
- Other drug classes used for treatment: chemotherapy, immunotherapy, bone metastases-targeted agents and PARP inhibitors
- Dynamic late-phase development pipeline that spans a wide range of drug classes, including novel classes, with significant potential for drug developers to target large number of drug-treatable cases of hormone-sensitive and castration-resistant prostate cancer (CRPC)

Unmet patient needs

Patients with prostate cancer would benefit from therapies with greater effectiveness, targeting predictive biomarkers with new MOAs and that prevent or delay progression to CRPC.



Relugolix
TAK-385; Orgovyx; Relumina
Oncology – prostate cancer
Reproductive health –
endometriosis & uterine fibroids

Market overview

>60%

of women with a confirmed
endometriosis diagnosis are
drug-treated

13M+

women aged 15–54 years
worldwide have confirmed
or suspected endometriosis

50M+

women aged 20–54 years
worldwide have uterine fibroids

Hysterectomy is currently
the only definitive cure for
uterine fibroids, but it also
results in permanent loss
of childbearing capability.

Reproductive health –
endometriosis

About the endometriosis market

- Elagolix (Orilissa), an oral GnRH antagonist, first and only drug to be approved by the U.S. FDA (August 2018) to treat endometriosis-related pain
- Surgical options: excision or ablation, hysterectomy with concurrent oophorectomy
- First-line therapies for endometriosis-related pain: hormonal contraceptives and NSAIDs
- Second-line therapies for endometriosis-related pain: GnRH agonists (e.g., Lupron)
- Large drug-treated population as a sizable target for developers of novel therapies

Unmet patient needs

There are few safe, long-term medical treatments, particularly non-hormonal or non-invasive options, for the management of endometriosis-related pain. Many treatments have undesirable menopause-like side effects (hot flashes, headache, nausea). Due to an increasing proportion of women delaying childbearing until later in life, there is also demand for uterus-sparing treatments.

Reproductive health –
uterine fibroids

About the uterine fibroid market

- Elagolix (Oriahnn): first and only GnRH antagonist approved by the U.S. FDA (June 2020) to treat uterine fibroids
- Cornerstones of medical management for uterine fibroids: hormonal contraceptives, GnRH agonists, tranexamic acid, NSAIDs, leuprolide and ulipristal (Europe only)
- Surgical options: hysterectomy, myomectomy and minimally invasive procedures such as uterine artery embolization, myolysis and endometrial ablation

Unmet patient needs

There are few safe, long-term medical treatments for uterine fibroid management, and rebound fibroid growth can occur once treatment ends. Patients are reliant on therapies that are safe but less effective, are effective but with a suboptimal safety profile, or have menopause-like side effects (hot flashes, headache, nausea). Due to an increasing proportion of women delaying childbearing until later in life, there is also demand for uterus-sparing treatments.



Relugolix
TAK-385; Orgovyx; Relumina
Oncology – prostate cancer
Reproductive health –
endometriosis & uterine fibroids

Analysis

Why is it a drug to watch?

Its potential use for three indications increases its chances of success. The oral formulation (daily administration) provides advantages over the injectable (administered every 3 months) GnRH agonist competitors, including convenience and better management of side effects. Demonstrated to be efficacious and comparatively safe, relugolix provides another option for medical management and might prevent or delay the need for surgical treatment.

- Although it will be first to market in the E.U., it is a smaller commercial opportunity
- Its uptake for prostate cancer will likely be modest, despite its entry as the first and only GnRH antagonist approved for prostate cancer, owing to fierce competition from the well-established GnRH agonists and Firmagon (injectable GnRH antagonist), and sales will be further constrained by the expected entry of generic alternatives

What to watch

Uptake across all three indications might be slow due to the entrenched first-line drug therapies and physician reluctance to prescribe because of the potential long-term side effects.

What you need to know

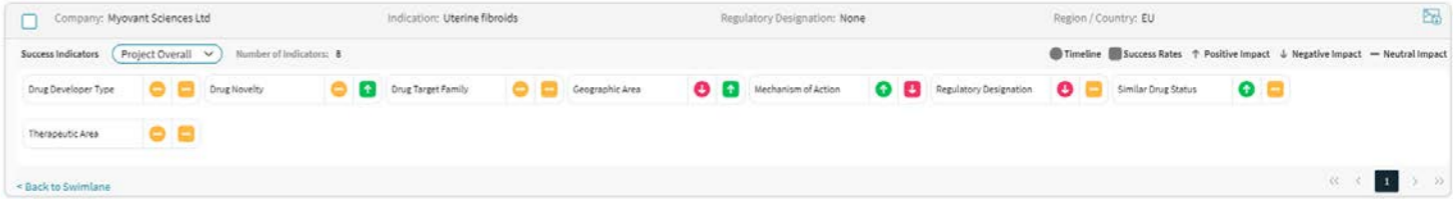
- For women with few effective medical management options for uterine fibroids and endometriosis, relugolix is promising for its efficacy and ease of use. However, long-term use of GnRH antagonists is hampered by hypoestrogenic side effects, including bone loss
- As the second-to-market GnRH antagonist for both endometriosis and uterine fibroids in the U.S., it will compete with AbbVie's Orilissa/Oriahnn, which had combined sales of \$125M in 2020

\$1.48B
expected sales in 2025

"Using birth control pills continuously can help the majority of the endometriosis-related pain. GnRH antagonists are likely to be used in the second line following birth control pills, and they have the potential for long-term use."

Gynecologist,
United States

Based on Cortellis data, relugolix is predicted to reach next approval in the E.U.



Source: Cortellis Competitive Intelligence, Drug Timeline & Success Rates
Prediction current as of January 26, 2021

This key emerging therapy is the first in the market to specifically address high-risk cases of chronic heart failure with reduced ejection fraction (HFrEF), who were often excluded from clinical trials of other HFrEF treatments.

About vericiguat

- Developed by Bayer AG and Merck & Co
- Soluble guanylate cyclase stimulator
- In the U.S., indicated for treatment of adults with chronic HFrEF (approved Jan 2021) following hospitalization for HF or receiving outpatient intravenous diuretics
- Undergoing MAA/NDA review by the EMA, PMDA and Chinese National Medical Products Administration (NMPA)

Vericiguat

Market overview

30%

of HFrEF patients are
rehospitalized within
three months

25%

expected increase in
prevalence of heart failure
in the U.S. by 2030

About the HFrEF market

- Crowded, competitive market that has been highly genericized for decades and consists of multiple effective treatment options
- Recent approvals of major new drugs for HFrEF include Entresto (sacubitril/valsartan) in 2015 and Farxiga (dapagliflozin) in 2020
- Differentiation necessary for new entrants to be successful

Unmet patient needs

HF (heart failure) remains associated with high mortality, morbidity and hospitalization rates. Patients with worsening HFrEF are at the highest risk of re-hospitalization and mortality, and treatments evaluated specifically for this subpopulation have been lacking.



Vericiguat
BAY-1021189;
MK-1242; Verquvo
Cardiovascular – heart failure

Analysis

Why is it a drug to watch?

The phase 3 VICTORIA trial demonstrated a clear reduction in hospitalization rates and a trend toward reduction in cardiovascular (CV) mortality in patients with severe, deteriorating HFrEF, leading to its approval to treat HFrEF in the U.S. For these patients, treatments that reduce hospitalizations and CV deaths remains an unmet need.

Because vericiguat's mechanism of action is distinct from current HF therapies, it can be prescribed as add-on therapy with little risk of severe side effects. Drug switching or new drug initiation for chronic HF patients is most common post-hospitalization, which is expected to accelerate vericiguat's uptake compared with drugs that should be initiated in stable patients, especially given its ease of use, once-daily oral dosing and simple titration.

What you need to know

- Vericiguat's novel mechanism of action should result in its acceptance as an add-on therapy to existing treatments and will be less exposed to direct competition from typical low-cost HF therapies
- It will likely find its niche among high-risk HFrEF patients, become a welcome addition to the treatment armamentarium and expand their treatment options

What to watch

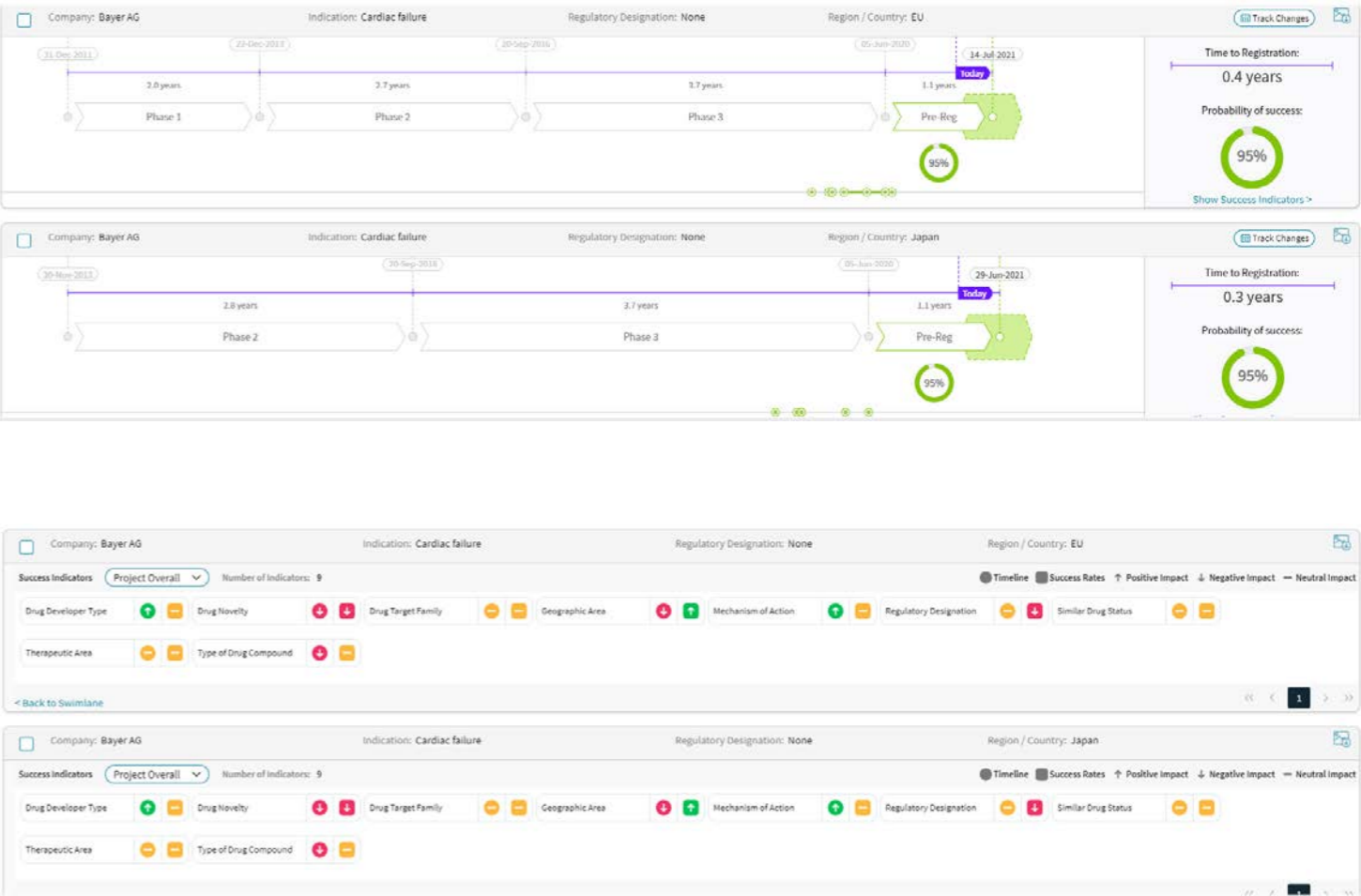
Competition from established first-line agents, a limited target patient population and payer hesitance for reimbursement could result in slow uptake and impact vericiguat's blockbuster status.

\$1.21B
expected sales in 2025

"The target population for vericiguat is a pretty high-risk group of patients. I don't think we have the data to suggest that we should use it widely in all heart failure patients, but I think this drug holds promise for people who are failing the standard of care and are coming to the hospital with worsening heart failure."

Cardiologist,
United States

Based on Cortellis data, vericiguat is predicted to reach its next approvals simultaneously in Japan and the E.U.



Source: Cortellis Competitive Intelligence, Drug Timeline & Success Rates
Prediction current as of January 26, 2021

COVID-19



Vaccines for SARS-CoV-2 infection (COVID-19)

Prevention and treatment of SARS-CoV-2 infection remain paramount to ending the COVID-19 pandemic.

Yet, more than a year after we first heard of the virus, it seems as if we are faced with more questions than answers: What is the optimal vaccination strategy? How does changing political environments affect distribution and uptake of vaccines? Do we have the manufacturing capacity to supply enough vaccine for the global population? How long will post-vaccination immunity last? Will vaccines be effective against new strains? Will we have to adjust vaccines annually, as we do for the flu? The list goes on.

Answering these questions is challenging for many reasons. New information and data become available nearly daily. Responses and strategies differ by country, public opinions of vaccine roll-out can affect government strategies in the "race to vaccinate" and the effectiveness of non-pharmaceutical intervention strategies (e.g., social distancing, testing, contact tracing) depends on governmental policy and human behavior.

One thing is for certain: Success will depend on continued responsiveness and collaboration. The solution might not be a single vaccine, but a vaccination strategy that accounts for the need to quickly pivot for new strains (as mRNA and viral vector vaccines could do) and the differing geographic situations. The Johnson & Johnson vaccine provides opportunities for developing countries, where a single-dose vaccine without extensive cold-chain requirements is suited to areas with limited infrastructure. In addition, effective treatment options are of the utmost importance for patients in urgent need of care.

Partnerships, such as Sanofi announcing its intent to manufacture the BioNTech/Pfizer vaccine, will be critical to ensuring capacity. And approval of the mRNA vaccines from Pfizer and Moderna, and the associated investment in facilities, will enable the technology use in other areas, like the recently announced mRNA influenza vaccine.

In this section, we review vaccines granted emergency use authorizations/conditional approvals as of February 10, 2021. We'll be monitoring the progress of near-term candidates like those from J&J and AstraZeneca. For complete coverage of the race to develop SARS-CoV-2 vaccines and treatments, please visit [BioWorld™](#)

AZD-1222

AstraZeneca/
University of Oxford

Two-dose recombinant viral vector vaccine

Development status

- Emergency use/conditional marketing authorizations granted in multiple countries
- Phase 3 clinical trials underway in Brazil, Chile, Colombia, Japan, Mainland China (sublicensed to Shenzhen Kangtai Biological Products), Peru, Russia, South Africa and the U.S.
- Korea Disease Control and Prevention Agency (KDCA) reviewing application for emergency use

Distribution

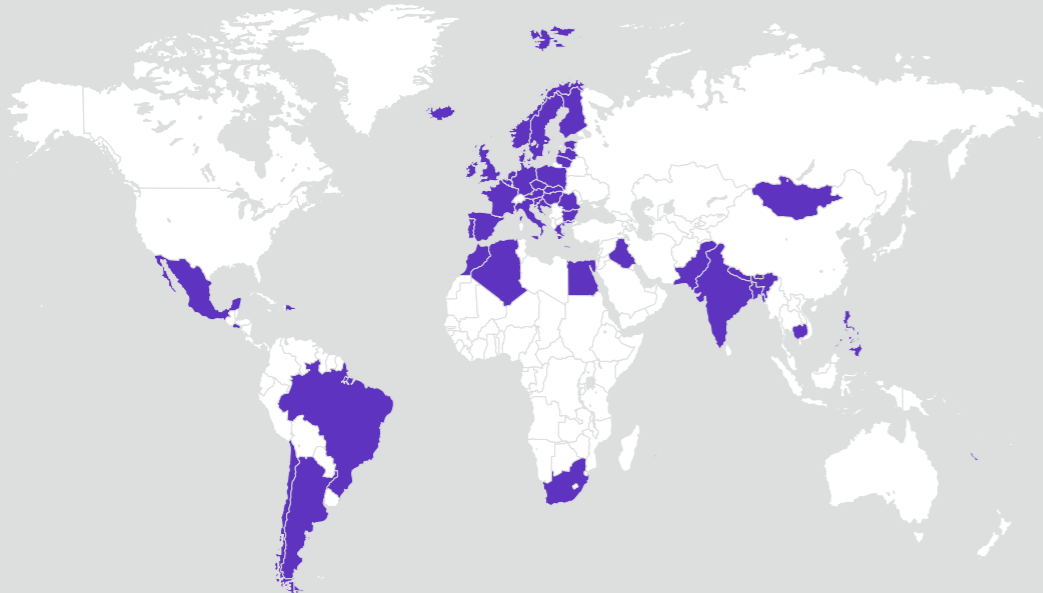
The vaccine is well-tolerated, easily distributed, storable at refrigerator temperatures and easily administered but there is some concern about its efficacy, which is as low as 59.5% as per protocol and as high as 90% with a prime-boost regimen that is not included in the planned protocol. Data are lacking for older patients (>55 years).

Deals

34

active deals

Emergency use authorizations granted in:



BBIBP-CorV

Beijing Institute of Biological
Products Co. Ltd/Sinopharm

Two-dose, inactivated vaccine

Development status

- Emergency use/conditional marketing authorizations granted in multiple countries
- Phase 3 clinical trials underway in Argentina, Egypt, Jordan and Peru

Distribution

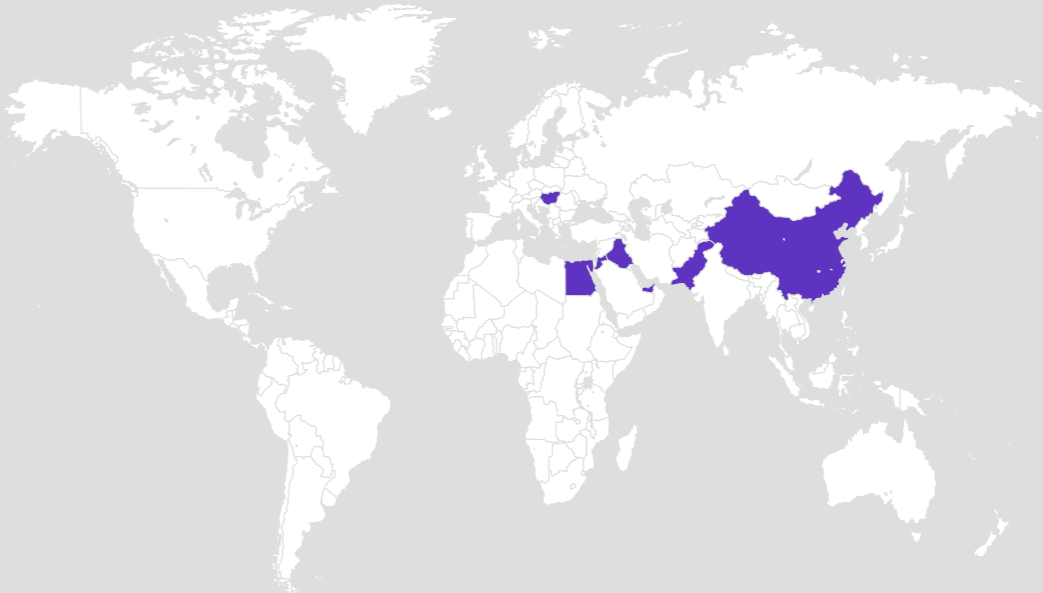
The vaccine is easily distributed and stored. While it has a reported 79% efficacy when administered per protocol, it is associated with a lower cost that could be attractive to low-income countries.

Deals

10+

procurement contracts with countries including Algeria, Argentina, Brazil, Egypt, Indonesia, Malaysia, Mexico, Morocco, Pakistan, Peru, Senegal, Thailand, Turkey and Ukraine

Emergency use authorizations granted in:





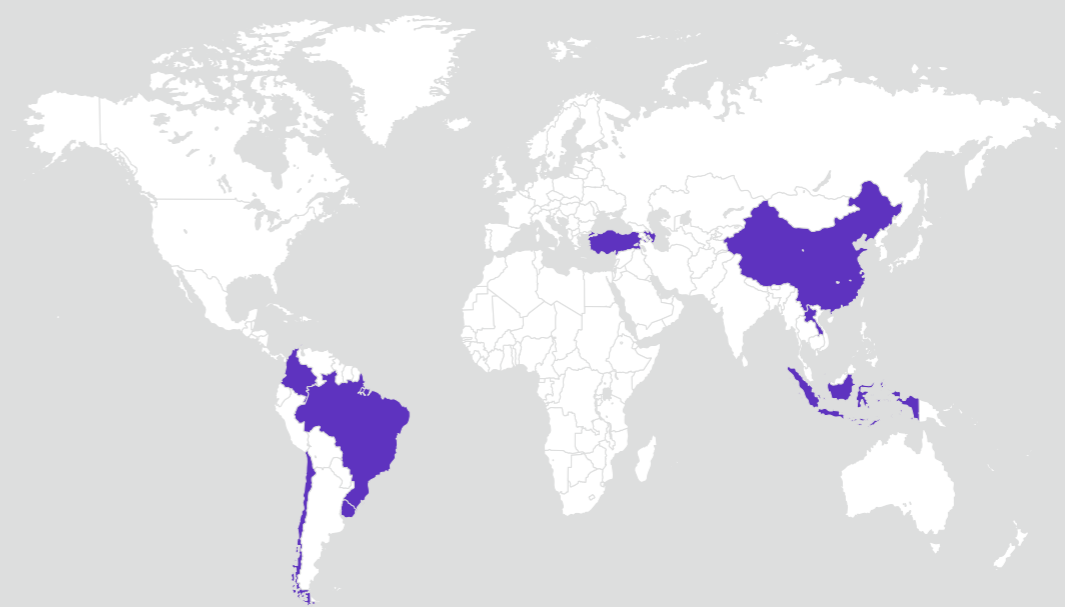
CoronaVac

Sinovac Biotech Ltd.

Two-dose, inactivated vaccine

Development status	Distribution	Deals
<ul style="list-style-type: none">• Emergency use/conditional marketing authorizations granted in multiple countries• Phase 3 clinical trials underway in multiple countries	<p>The vaccine is easily distributed and stored. The efficacy remains to be determined, with rates as low as 50% reported by Brazil, but the vaccine can reportedly reduce the need for hospitalization and the most severe forms of COVID-19 by 100%.</p>	<p>11+ procurement contracts with 11+ countries</p>

Emergency use authorizations granted in:



Gam-COVID-Vac

Sputnik V; Gamaleya
Research Institute

Two-dose, heterologous recombinant
adenovirus vaccine

Development status

- Emergency use/conditional marketing authorizations granted in multiple countries
- Phase 3 clinical trials underway in Belarus, the United Arab Emirates, Venezuela and India

Distribution

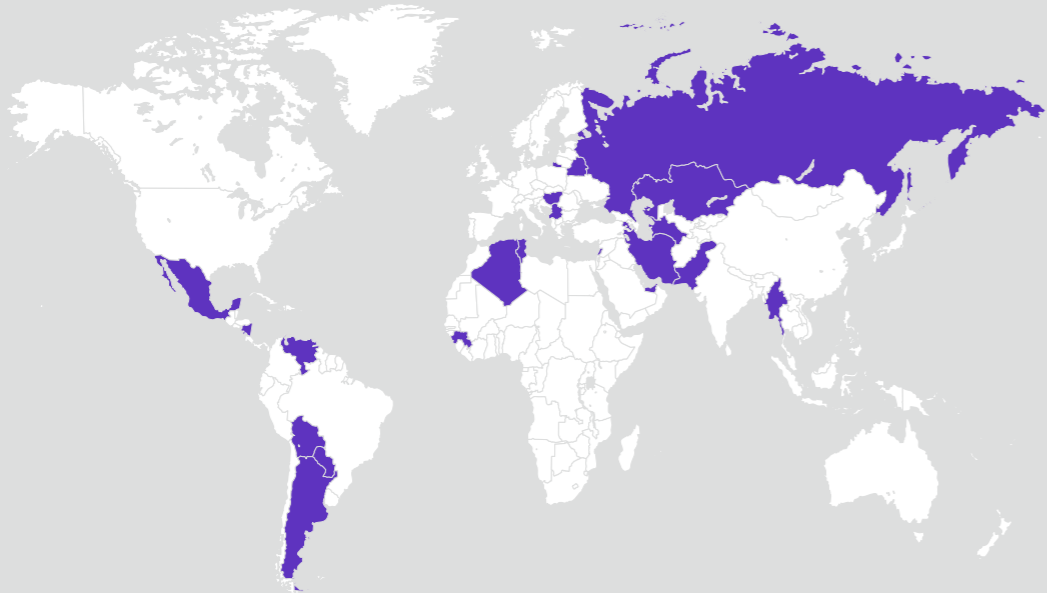
The vaccine is well-tolerated and easily administered, with a reported 91.6% efficacy when administered per protocol but it does require storage at freezer temperatures.

Deals

15

active deals

Emergency use authorizations granted in:



mRNA-1273

Moderna
Therapeutics/NIAID

Two-dose, lipid nanoparticle RNA vaccine

Development status

- Emergency use/conditional marketing authorizations granted in multiple countries
- Phase 1/2 trial underway in Japan

Distribution

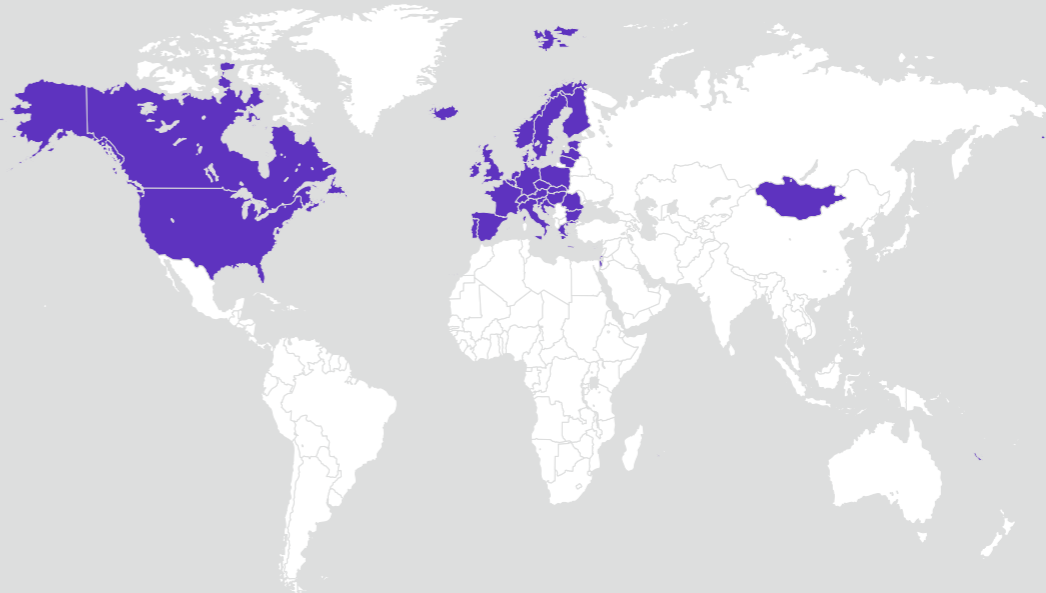
The vaccine is well-tolerated, easily distributed, storable at refrigerator temperatures and easily administered, with a reported 94% efficacy when administered per protocol.

Deals

26

active deals

Emergency use authorizations granted in:



Tozinameran

Comirnaty; BioNTech
SE/Pfizer Inc

Two-dose, lipid nanoparticle RNA vaccine

Development status

- First COVID-19 vaccine approved worldwide
- First-in-class lipid nanoparticle vaccine
- Emergency use/conditional marketing authorizations granted in multiple countries
- Phase 1 clinical trial (sublicensed to Shanghai Fosun Pharmaceutical [Group] Co Ltd) underway in Mainland China

- Phase 3 clinical trials underway in Argentina, Brazil, South Africa and Turkey
- Japan PMDA reviewing an application for emergency use

Distribution

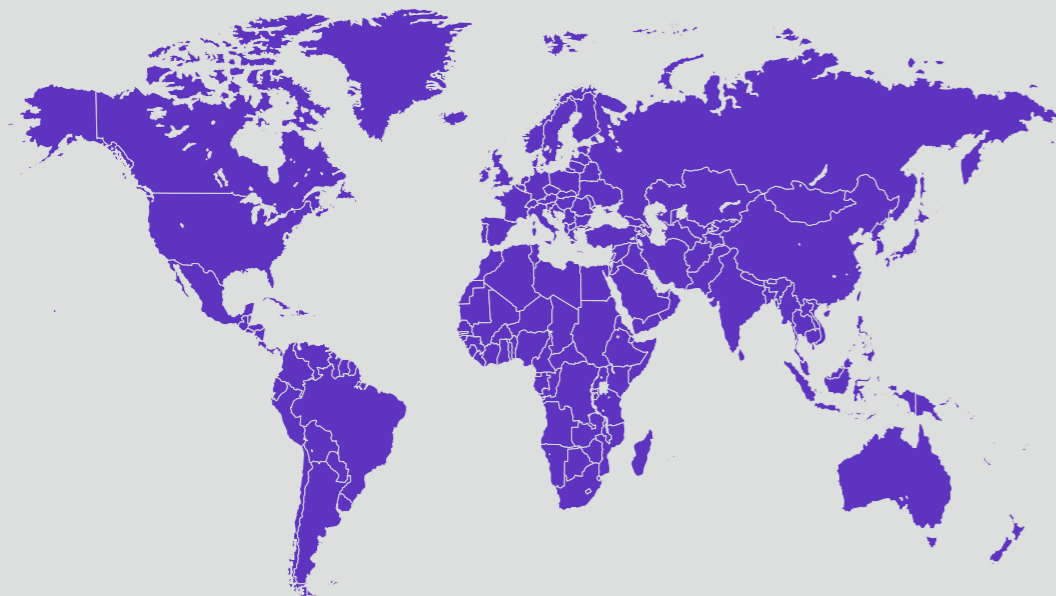
The vaccine is well-tolerated, is easily administered and has a reported 95% efficacy when administered per protocol, but it requires ultra-cold chain storage.

Deals

18

active deals

Emergency use authorizations granted in:





Looking ahead

COVID-19 is set to impact drug development going forward, both for better and for worse.

Little more than a year into the COVID-19 pandemic, encouraging developments on the vaccine front are coming so fast it's hard to keep up, with a handful of vaccines already in distribution and candidates from like Novavax and Johnson & Johnson posting solid efficacy numbers. This remarkable turnaround reflects, in part, huge adjustments made on the fly by industry and regulators alike to accelerate development. Learnings from some of these adjustments are likely to shape biopharma R&D and commercialization well beyond the immediate crisis of the COVID-19 pandemic, including:

- **Faster clinical trials:** Meeting the urgency of the moment required that regulators and drug developers rethink the traditional sequential model of conducting clinical trials, operating instead with multiple overlapping trials and phases running in tandem. Some of the factors that enabled companies to collapse vaccine development from years to months safely are specific to vaccines – for example, the development of mRNA and other vectors, for example, and recent leaps in our understanding of viruses and immunology, for example. Others may well bleed over into the development of small and large molecule therapeutics.

- **A surge in investment:** Even as the world economy shuddered, investment in biotech soared last year to nearly \$134 billion¹, while biopharmas raised nearly \$7 billion in seed and series A rounds, with much of that activity focused on oncology and infectious diseases.

- **A more collaborative approach:** One early ray of hope amid the gloom of the pandemic's onset came as biopharma competitors formed consortia and joint ventures to pool data, share information, and speed the development of vaccines and treatments for the disease.

- **More remote care and consultation:** Much of life has gone virtual, from patient care to clinical trial check-ins to biopharma financing roadshows and payer negotiations. Some of this shift from in-person to digital will stick and could help to accelerate timelines going forward.

On the downside, however, social and travel restrictions have resulted in the disruption of at least 427 ongoing clinical trials¹, from delays and suspensions to terminations. And while FDA approvals for 2020 came in at a robust 46 new molecular entities, tracking with the previous year's, there was a substantial decline in new drug and biologic applications and efficacy supplements for the first half of the year, suggesting that a corresponding dip in approvals is likely for 2021.

1. Ward, M. (2021) Biotech set for good start to 2021, Clarivate

About Clarivate

Clarivate™ is a global leader in providing solutions to accelerate the lifecycle of innovation. Our bold mission is to help customers solve some of the world’s most complex problems by providing actionable information and insights that reduce the time from new ideas to life-changing inventions in the areas of science and intellectual property.

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