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ASIA EDITION

Clarivate Identifies fifteen potential drugs to watch in 2023 that could become blockbuster by 2027

10 January 2023 | Analysis

The annual Drugs to Watch™ analysis report identifies 15 late-stage drugs entering the market or launching key indications in 2023 which are predicted to achieve blockbuster status by 2027 or be clinical game changers with forecast to deliver annual sales of more than $1 billion within five years.

Clarivate Plc, has announced the release of its 10th annual Drugs to Watch™ report sharing in-depth predictive analysis of drugs with the potential to transform treatment paradigms and serve unmet patient needs. More than 70 drugs have been identified as Drugs to Watch in an ever-evolving drug innovation landscape.

Among new drugs and biologics that have either won approval or are poised to, Clarivate has identified 15 treatments likely to achieve blockbuster status in the next five years or transform paradigms to meet unmet patient needs. This year's analysis identifies drugs entering the market or launching key indications in 2023 expected to become blockbusters by 2027 or to change the lives of millions of patients. Clarivate analysts identified 15 late-stage experimental treatments that are each forecast to deliver annual sales of more than $1 billion within five years. Among these promising developments are treatments for HIV, Parkinson's disease, Crohn's disease, alopecia, multiple myeloma, and breast cancer, among other conditions.

The 2023 Drugs to Watch, are:

Bimekizumab (BIMZELX®) developed by UCB- Bimekizumab is the first dual IL-17 A/F inhibitor to treat moderate to severe plaque psoriasis. Phase 3 trial results showed superior skin clearance outcomes than existing treatments. Its less-frequent dosing schedule and good safety profile will likely be attractive to clinicians and patients.

Capivasertib (AZD5363) developed by AstraZeneca- For patients with breast cancer, Capivasertib is a novel, highly potent, selective ATP-competitive pan-AKT kinase inhibitor that exerts similar activity against the three isoforms AKT1, AKT2 and AKT3. Positive data have emerged from early-phase trials, with clinical benefit to patients irrespective of their PIK3CA/AKT1/PTEN mutational status, and several phase 3 trials are now underway.

Daprodustat (GSK1278863/Duvroq) developed by GSK plc.- Daprodustat belongs to a novel class of oral treatments for **chronic kidney disease (**CKD)-related anemia and is a HIF-PHI developed to treat anemia associated with CKD, which has a high incidence rate and few effective, safe treatment options. Already available for CKD-related anemia in Japan, its uptake has been impressive.

Deucravacitinib (SOTYKTU™/BMS-986165) developed by Bristol Myers Squibb- As a first-in-class oral, targeted agent that selectively inhibits tyrosine kinase 2 (TYK2), a Janus kinase (JAK) family member that mediates cytokine-driven immune and inflammatory signals, it has the potential to fill a gap in the treatment armamentarium for plaque psoriasis.

Foscarbidopa/foslevodopa (ABBV-951) developed by AbbVie- Foscarbidopa/foslevodopa is a novel reformulation of the gold-standard Parkinson's disease treatment (carbidopa/levodopa) delivered via a subcutaneous pump for the treatment of motor fluctuations in advanced Parkinson's disease. In addition to serving a niche group of patients with high unmet need, it offers better efficacy than orally administered carbidopa-levodopa, dosing flexibility and a more convenient pump than existing and upcoming competitors.

LEQEMBI™ (BAN2401) developed by Eisai Co Ltd and Biogen Inc, and Donanemab (LY-3002813), developed by Eli Lilly and Company- LEQEMBI and Donanemab are poised to help treat early-stage Alzheimer's disease. Supported by landmark clinical data from a phase 3 trial, next-in-class anti-A? monoclonal antibody (MAb) LEQEMBI has recently received accelerated approved by the U.S. and has ex-U.S. launches. Donanemab, and others in the class (e.g., Roche's gantenerumab), may follow suit pending the results of ongoing trials.

Lenacapavir (Sunlenca®/GS-6207) developed by Gilead Sciences Inc.- Approved in Europe and under evaluation by the U.S. Food and Drug Administration (FDA), lenacapavir is the first-in-class, long-acting HIV-1 capsid inhibitor approved to treat multi-drug resistant (MDR) HIV in people who have been heavily treated, a patient population with unmet medical need. Also currently being investigated to treat HIV and for pre-exposure prophylaxis (PrEP), its infrequent dosing and self-administration will likely make it a favored choice in a population with treatment adherence challenges.

Mirikizumab (LY-3074828) developed by Eli Lilly and Company - Mirikizumab, a monoclonal antibody targeting the p19 subunit of IL-23, will likely be first-in-class for ulcerative colitis and the third in the class approved for Crohn's disease. Part of a set of emerging therapies with novel mechanisms of action, it will contribute to the growing market share held by these therapies.?

Pegcetacoplan (EMPAVELI®/ASPAVELI®/APL-2) developed by Apellis Pharmaceuticals Inc. - Pegcetacoplan has launched already in the United States and Europe for Paroxysmal nocturnal hemoglobinuria (PNH), a rare hematological disease. As one of the few drugs to have completed phase 3 trials for GA, pegcetacoplan is expected to be the first drug to launch for geographic atrophy (GA)or "dry late age-related macular degeneration (AMD)," which has no approved pharmacotherapy.

Ritlecitinib (PF-06651600) developed by Pfizer Inc.- Ritlecitinib will likely benefit from its first-in-class status, rapid onset of action and expected label for both adults and adolescents, potentially providing an effective option to stimulate hair growth in a stigmatizing disease **-** Alopecia areata.

Sparsentan developed by Travere Therapeutics Inc - Sparsentan is a first-in-class, orally active, single molecule that functions as a high-affinity, dual-acting antagonist of both endothelin type A (ETA) and angiotensin II subtype 1 (AT1) receptors, which are associated with progression of kidney disease. Its development for IgA nephropathy and focal segmental glomerulosclerosis (FSGS) promises to halt that progression for many patients and fills a gap in the treatment armamentarium.

Teclistamab (TECVAYLI®/JNJ-64007957) developed by Janssen Pharmaceutical Companies of Johnson & Johnson - After receiving conditional approval from the EC (European Commission), teclistamab is the first-in-class bispecific antibody targeted to B-cell maturation antigen (BCMA) to treat multiple myeloma. Ongoing phase 3 trials are expected to provide confirmation of clinical benefit in teclistamab's approved setting and lead to label expansions in other multiple myeloma patient populations, including in combination with other approved agents.

Teplizumab (TZIELD™/PRV-031) developed by Provention Bio Inc- Teplizumab is the first immunotherapy to launch for T1DM and is a landmark drug given its potential ability to preserve beta cell function and delay the need for insulin treatment in those with type 1 diabetes mellitus (T1DM).

Valoctocogene roxaparvovec (ROCTAVIAN™/BMN-270) developed by BioMarin Pharmaceutical Inc -Approved by the European Commission (EC) in August 2022, valoctocogene roxaparvovec is also poised to be the first gene therapy to launch in the United States for severe hemophilia A. Treatment benefit is expected to last for years, reduce the number of bleeding events, minimize the need for replacement factor VIII (FVIII) and negate the use of otherwise burdensome prophylaxis treatment.