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2023 to be highly lucrative for drug developers across therapeutic areas: Report

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Citeline shares insights on a longer-term outlook at some key late-stage drugs projected to hit the market in 2023



Citeline (formerly ‘Informa Pharma Intelligence’) has recently published the “Key Potential Drug Launches in 2023” report sharing insights on a longer-term outlook of some key late-stage drugs projected to hit the market in 2023.

Chronic Heart Failure (CHF) remains a key area of attention for drug makers. In this scenario, Furoscix is a reformulation of the diuretic furosemide which has been developed for the treatment of decompensated heart failure and designed to be self-administered in the outpatient setting through a subcutaneous infusion via a wearable, on-body drug delivery system. Currently, the Prescription Drug User Fee Act (PDUFA) date for Furoscix is set at October 8 2022 following a resubmission of an NDA in April 2022 which included data from the Phase III FREEDOM HF trial, where the overall and heart failure-related costs of treating congestion in patients with CHF were investigated.

Simultaneously, Omecamtiv Mecarbil is another soon-to-be-launched drug, which will provide additional means of improving outcomes on top of the standard of care for those patients with more advanced stages of CHF.

In the Oncology space, for Bone Marrow Transplant and Stem Cell Transplant, Gamida Cell’s omidubicel is a nicotinamide (NAM)-enabled stem cell therapy being studied for use in allogeneic hematopoietic (bone marrow) stem cell transplants for patients with hematologic malignancies like acute lymphocytic leukemia.

In June 2022, Gamida Cell completed its submission to the FDA for omidubicel’s biologics license application, with a final decision expected in June 2023 if there are no delays.

Breyanzi has demonstrated encouraging results in the Phase I/II TRANSCEND-CLL-004 trial, reporting higher observed overall response rates compared to other investigational CD 19-directed CAR-T therapies, such as Kymriah. Breyanzi looks set to emerge as a revolutionary option for this last-line treatment setting, pending its supplemental approval in 2023.

For Haematology, Vertex had announced that global regulatory filings for exa-cel (CTX001) in transfusion-dependent beta-thalassemia (TDT) and sickle cell disease are expected by the end of 2022 which if successful, could in 2023 make it the first CRISPR/Cas 9 based product ever approved, an important boost for the gene editing technology.