Media Update

CHMP recommends approval of Xenpozyme® (olipudase alfa), the first and only treatment for ASMD

- Recommendation based on positive results from two clinical trials in which Xenpozyme provided improvement across multiple non-CNS clinical manifestations of ASMD in pediatric and adult patients
- ASMD is a rare, progressive, and potentially life-threatening disease with no approved treatments in Europe

Paris, May 19, 2022. The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for Xenpozyme® (olipudase alfa), recommending that this investigational enzyme replacement therapy be approved in the European Union (EU) for the treatment of non-central nervous system (non-CNS) manifestations of acid sphingomyelinase deficiency (ASMD) in pediatric and adult patients with ASMD type A/B or ASMD type B.

The positive CHMP opinion is based on data from the ASCEND and ASCEND-Peds clinical trials, demonstrating that Xenpozyme showed robust and clinically relevant improvement in lung function (as measured by diffusing capacity of the lung for carbon monoxide, or DLco) and reduced spleen and liver volumes, with a well-tolerated safety profile in adults and children with ASMD.

The EMA previously awarded olipudase alfa the PRIority MEdicines designation, also known as PRIME, and the application was reviewed under the EMA's accelerated assessment, intended to aid and expedite the regulatory process for investigational medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options. The European Commission will review the CHMP recommendation and is expected to make a final decision in the coming months.

About Xenpozyme

Xenpozyme® (olipudase alfa) is an enzyme replacement therapy designed to replace deficient or defective acid sphingomyelinase (ASM), an enzyme that allows for the breakdown of sphingomyelin. Accumulation of sphingomyelin in cells can cause harm to the lungs, spleen, and liver, as well as other organs, potentially leading to early death. Xenpozyme is currently being investigated in pediatric and adult patients to treat non-CNS manifestations of ASMD. Xenpozyme has not been studied in ASMD type A patients.

In March 2022, Xenpozyme was approved in Japan under the SAKIGAKE (or "pioneer") designation, marking the first approval for olipudase alfa anywhere in the world. In the United States, where olipudase alfa received Breakthrough Therapy designation, the Food and Drug Administration (FDA) has extended its review of the Biologics License Application (BLA) by three months, with a new target action date for the FDA decision (PDUFA date) of October 3, 2022.

About ASMD

Historically known as Niemann-Pick disease types A, A/B, and B, ASMD is a rare, progressive, and potentially life-threatening genetic disease. ASMD represents a spectrum of disease, with two types that may represent opposite ends of a continuum referred to as ASMD type A and ASMD type B. ASMD type A/B is an intermediate form that includes varying degrees of central nervous system (CNS) involvement.

About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

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