AMIDEBIO

U.S. FDA grants rare pediatric disease designation to AmideBio's glucagon analog for the treatment of congenital hyperinsulinism

BOULDER, CO, August 20, 2020 – AmideBio, LLC, a privately held biopharmaceutical company, announced today that the US Food and Drug Administration (FDA) Offices of Pediatric Therapeutics and Orphan Products Development granted a rare pediatric disease designation to AmideBio's glucagon analog (AB-G023) for the treatment of congenital hyperinsulinism (CHI). AB-G023 is a solution stable, soluble glucagon analog designed to overcome the limitations of glucagon – an effective treatment for CHI, but rendered impractical for long term administration given its instability in solution. The development of AB-G023 was funded through Small Business Innovation Research (SBIR) Phase I and II grants from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Division of the National Institutes of Health (NIH). It was granted Orphan Drug designation in April of this year.

Under the FDA's rare pediatric disease designation program, a sponsor who receives a product approval for a "rare pediatric disease" may be granted a priority review voucher from the FDA. Subject to FDA approval of AB-G023 for the treatment of CHI, AmideBio would be eligible to receive a voucher that can be redeemed to receive priority review for a subsequent marketing application for a different product candidate or can be sold or transferred to another entity.

"This rare pediatric disease designation for AB-G023 shows continued recognition by the FDA of the importance of identifying an improved treatment for CHI patients and their parents," said Pawel Fludzinski, CEO and President of AmideBio. "Amidebio's AB-G023 has the potential to be more readily administered, including for use in pumps."

About Congenitial Hyperinsulinism

Congenital hyperinsulinism is a rare disease that affects newborns and children. It results in persistent hypoglycemia which can lead to serious neurological complications including seizures and brain damage. It is a caused by a defect in the pancreas which results in patients having severe hypoglycemia due to the over production of insulin. Approximately one in every 50,000 new births are diagnosed with CHI each year. Existing pharmaceutical treatments are less than satisfactory, often necessitating the surgical intervention of partial or full pancreatectomies, the latter resulting in the patient developing Type 1 diabetes.

About AmideBio

AmideBio has a pipeline of novel biotherapeutics targeting metabolic disease. This pipeline was generated by leveraging its core competencies in intelligent design of drug candidates together with its proprietary BioPure™ technology which delivers high purity and difficult-to-manufacture peptides of any length with unprecedented purity for the pharmaceutical and biotech industry.

Contact:
Pawel Fludzinski, Ph.D.
CEO & President
T: (505) 469-8466
pawel.fludzinski@amidebio.com
www.amidebio.com