



U.S. FDA grants orphan drug designation to AmideBio's glucagon analog for the treatment of congenital hyperinsulinism

BOULDER, CO, April 23, 2020 – AmideBio, LLC, a privately held biopharmaceutical company, announced today that the US Food and Drug Administration (FDA) Office of Orphan Products Development granted an orphan drug designation to AmideBio's glucagon analog (ABG-023) for the treatment of congenital hyperinsulinism (CHI). ABG-023 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 ABG-023 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).

“This orphan drug designation is an important step for AmideBio's development of ABG-023 and for CHI patients and their parents. Glucagon has been shown to be a potentially game-changing treatment for these patients if it can be more readily administered, including for use in pumps,” said Pawel Fludzinski, CEO and President of AmideBio. “Our initial studies of ABG-023 have shown it to have great promise in overcoming the shortfalls of glucagon without sacrificing efficacy. This designation will serve to accelerate our development efforts”.

Congenital 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 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.

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