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Diamyd Medical gains market research findings to guide U.S. commercial strategy

Market research including initial interviews with US health care practitioners as well as US payers demonstrated a strong willingness to consider prescribing the investigational precision medicine Diamyd® for Type 1 Diabetes and pricing in the range of USD 200,000. Diamyd® is currently being evaluated in the registrational Phase 3 trial DIAGNODE-3 in patients recently diagnosed with Type 1 Diabetes that carry the HLA DR3-DQ2 haplotype.

"These results both confirm and exceed our previous insights regarding pricing and the market potential of Diamyd in the US", says Ulf Hannelius, CEO of Diamyd Medical. "The precision medicine focus, strong safety profile and the simplicity of the administration resonate strongly and make Diamyd a very attractive potential new treatment option for type 1 diabetes".

Pricing Insights: The research, undertaken by the US-based consultancy Kondrad Consulting Group^a, involved detailed interviews with both national and regional payers, collectively responsible for healthcare coverage of approximately 77 million commercial lives in the United States. These interviews suggest a potential price range of USD 194,000 – 240,000 for Diamyd® based on effective delivery of its unique product profile targeted at a specific genetic subgroup of type 1 diabetes patients.

Healthcare Practitioner Feedback: Conversations with a select group of primary care, endocrinologist and interventional radiologist physicians shed light on various aspects of the patient journey and treatment preferences. The willingness to consider prescribing Diamyd® was very strong. Interventional radiologists, in particular, found the ultrasound guided injection procedure to be straightforward and virtually painless, aligning with previous observations made by Diamyd Medical.

Educational Needs and Market Preparation: The research highlighted some gaps in awareness regarding type 1 diabetes staging and the diversity in first-line therapy approaches. These findings underscore the importance of continuous educational efforts in tandem with the introduction of new treatments like Diamyd®. The research pointed to Integrated Delivery Networks (IDNs) as a natural and effective delivery channel for Diamyd® outpatient treatment. IDNs are networks of hospitals, physicians, and clinics covering a broad continuum of outpatient care from diagnostics to procedures to surgeries.

a. Kondrad Consulting Group, LLC, Sarasota, FL USA, www.kondradconsulting.com

About Diamyd Medical

Diamyd Medical develops precision medicine therapies for the prevention and treatment of Type 1 Diabetes and LADA (Latent Autoimmune Diabetes in Adults). Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. DIAGNODE-3, a confirmatory Phase III trial is actively recruiting patients with recent-onset Type 1 Diabetes in eight European countries and in the US. Significant results have previously been shown in a large genetically predefined patient group - in a large-scale meta-analysis as well as in the Company's European Phase IIb trial, where Diamyd® was administered directly into a lymph node in children and young adults with recently diagnosed Type 1 Diabetes. A biomanufacturing facility is being set up in Umeå for the manufacture of recombinant GAD65 protein, the active ingredient in the antigen-specific immunotherapy Diamyd®. Diamyd Medical also develops the GABA-based investigational drug Remygen® as a component in treatments of metabolic diseases. Diamyd Medical is a major shareholder in the stem cell company NextCell Pharma AB as well as in the artificial intelligence company MainlyAI AB.

Diamyd Medical's B-share is traded on Nasdaq First North Growth Market under the ticker DMYD B. FNCA Sweden AB is the Company's Certified Adviser.

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