EryDel Appoints Dr Esin Kosal, PhD, as Senior Vice President, Global Regulatory Affairs

Bresso (Milano); Italy – 30 November, 2020 - EryDel SpA, a global late-stage biotech company aimed at developing and commercializing therapies for the treatment of rare diseases delivered by its proprietary red blood cell technology, announced today the appointment of Esin Kosal as Senior Vice President, Global Regulatory Affairs.

Dr. Benatti remarked, "The addition of Dr. Kosal to the EryDel team comes at a critical time as the company prepares for the completion of EryDel's pivotal Phase 3 study ATTeST, the largest study ever conducted in ataxia telangiectasia (AT) and regulatory filing of its lead product EryDex. Dr. Kosal has extensive regulatory experience and an outstanding track record, having supported the advancement of multiple pharmaceuticals including orphan drugs through the regulatory approval processes".

Dr. Kosal has over 20 years of global regulatory experience with focus on the development, registration and successful launches of new chemical entities including rare disease products. With her in-depth knowledge in regulatory and drug development, she has contributed to the ever-evolving regulatory landscape for establishing global development programs. Most recently at Mitsubishi Tanabe Pharmaceuticals, Dr. Kosal led establishing the regulatory affairs strategies for development products. Her previous positions included serving as Vice President, Global Regulatory Affairs at Axovant Pharmaceuticals, where she oversaw the global regulatory affairs activities for Phase-2 and Phase-3 studies and NDA preparation. Additionally, as Global Regulatory Affairs Head at SKLSI Pharmaceuticals, she created and implemented global strategies during the development of multiple products including orphan drug application. She also held several leadership positions in global regulatory affairs at BMS, Pfizer, and Forest Labs. Dr. Kosal has a Ph.D. in molecular thermodynamics from the University of Pittsburgh. She studied Medicinal Chemistry as a Post-Doc researcher at Northeastern University. In addition, she earned two M.S. degrees in Chemical Engineering and Analytical Chemistry.

Dr. Kosal commented: "EryDel 's unique and novel technology applied to a diversified pipeline can offer invaluable contributions for the treatment of rare diseases with significant unmet needs. I am excited to join EryDel at this pivotal time in the company's history and to contribute to successfully filing and potential approval of the first therapy for the treatment of Ataxia Telangiectasia".

About Ataxia Telangiectasia (AT)

Ataxia Telangiectasia is a rare genetic disease caused by biallelic mutations in the ataxia telangiectasia mutated (ATM) gene, for which no established therapy is currently available. ATM encodes a PI3Kinase protein shown to play a pivotal role in response to DNA damage and cell cycle control. Homozygosity for ATM mutations result in a multi - systemic disorder, involving mainly the nervous and immune systems. The major clinical feature of AT is severe progressive neurodegeneration from early infancy. Specific features include progressive ataxia of the trunk and limbs, involuntary movements, oculomotor apraxia, difficulties with speech and swallowing, and delayed peripheral neuropathy. Other clinical features of patients with the classical phenotype include oculocutaneous telangiectasia, immunodeficiency with recurrent respiratory tract infections, radiosensitivity and an increased incidence of cancer.

About EryDel

EryDel SpA is a biotechnology company specialized in the development of drugs delivered through red blood cells (RBCs) by using a proprietary medical device technology. Its most advanced product, EryDex System (EDS) is under late stage development for the treatment of Ataxia Telangiectasia, a rare autosomal recessive disorder for which no established therapy is currently available. EryDex has received Orphan Drug designation for the treatment of AT both from the FDA and the EMA. A completed pilot Phase II trial in AT patients demonstrated statistically significant efficacy of EDS on both the primary and secondary efficacy measures. An international multi - center, Phase III pivotal study, ATTeST, is being conducted. EryDel has a pipeline of preclinical programs that use its proprietary RBC's delivery technology for the treatment of other rare diseases.

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