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Production of Drug-loaded Nano- and Microparticle Formulations with *ImSus*® Platform Technology

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ImSus® is a unique platform technology for the manufacture of drug-loaded polymeric nano- and microparticle formulations, which can be administered via different routes. *ImSus*® is a fast, simple and robust one pot process; all excipients used are either approved by the FDA for parenteral applications or generally regarded as safe (GRAS). Due to the new physical principle behind *ImSus*® technology, the formulations show no initial burst as well as very high drug loading and encapsulation efficiency.

Using *ImSus*® technology it was succeeded to develop the first microparticlebased controlled-release depot forms of goserelin-acetate, a drug that is mainly indicated for the treatment of hormone-related cancers like prostate cancer. The current dosage forms of goserelin-acetate - AstraZeneca's Zoladex® 3.6 mg or 10.8 mg for treatment periods of one month or three months, respectively - are implants, which are administered via large needle gauges (16G or 14G). The new microparticle-based depot forms (both, the one-month and the threemonth product) shall be administered via a significantly smaller needle gauge (25G), the smallest in its class. This will increase the patient compliance and convenience. In addition, the new depot forms will compete with current depot forms of leuprorelinacetate and triptorelin-acetate, drugs of the same class that are equivalently indicated. Though most of these competitors are likewise marketed as microparticle-based depot forms, only the new form allows for the manufacture without using carcinogenic solvents. Extensive pre-clinical data from comparative animal studies will be presented that demonstrates equivalent or even superior pharmacodynamic profiles (testosterone suppression).

Biography

Dr. Albayrak graduated in Physical Chemistry and completed his Ph.D. in 1985 from the Institute for Physical Chemistry at the Aachen University of Technology. After his research work at the Nuclear Research Centre in Juelich, Dr. Albayrak joined Schering in 1987 where he was in charge of developing controlled release formulations. With his expertise and inventions, Dr. Albayrak left Schering in 2000 and founded Actipac, which was later owned by Nektar Therapeutics. Since 2004 he is CEO of Alrise, a Berlin-based drug delivery company. He has written numerous scientific publications and was the inventor of Alrise's patents and patent applications.