

VPM5001

Soluferon[®] is a 2nd generation modified type-1 interferon with increased bioavailability, due to enhanced hydrophilic properties. It is well known that the major shortcomings of the currently marketed type-1 interferons, namely high hydrophobicity causing aggregation and antigenicity, have been attributed to their limited efficacy and tolerability. In order to improve the pharmacokinetic properties of the currently available type-1 interferon derivatives while retaining all pharmacodynamic properties, Soluferon[®] was designed such that the amino acid sequence of human interferon beta was changed in the non-functional portion of the molecule. Eight hydrophobic amino acids and one cysteine were replaced by hydrophilic serine moieties. As a result hydrophobicity was reduced and bioavailability was increased up to six-fold when compared to human interferon beta.

Higher bioavailability promises better efficacy and tolerability, as it has been clinically demonstrated that higher interferon beta doses lead to fewer relapses in MS. Furthermore, the absence of immunoreactive sequences, as demonstrated in in silico analyses of the amino acid sequence, indicate reduced antigenicity of Soluferon[®] as compared to marketed interferon beta. The intended use of Soluferon[®] has potential for the treatment of Multiple Sclerosis (MS), but also in viral diseases, such as Hepatitis C. MS alone represents a > 4 billion US\$ market. The improved properties of Soluferon[®] should result in a rapid and significant market penetration. A number of patents have been granted and VPM has obtained a worldwide exclusive license for the development and further out-licensing. The intellectual property is protected until 2018 worldwide. A GMP process including a proprietary cell line is in place and clinical trial material has been manufactured. The compound is presently in preclinical testing and it is planned to initiate the clinical phase I in 2011.

Several different molecules are presently in development. However, these are mostly early stage new compounds with lengthy development processes and high risk of failure. Soluferon[®] is a member of the well-established IFN beta class, yet has markedly improved properties. This makes Soluferon[®] a promising candidate for a better treatment of MS in the future.

The substance was developed at and patented by Fraunhofer-Institut für Grenzflächen- und Bioverfahrenstechnik, Stuttgart/Hannover. VPM holds the exclusive and worldwide license to this patent family.

Soluferon[®] is the registered international trademark of Vakzine Projekt Management GmbH (VPM).

Contact for products and licensing:

Dr. Leander Grode
+49 (0)511.169908-0

[grode\(at\)vakzine-manager.de](mailto:grode(at)vakzine-manager.de)