

**Xendo Manufacturing B.V. and Selexis S.A. offer an Integrated Drug Development concept for the biopharmaceutical industry**

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The Dutch based CMO and consultancy company, Xendo Manufacturing B.V. and the Swiss based cell line development company, Selexis S.A., have developed an Integrated Drug Development program which offers significant acceleration of clinical programs.

Drs. Ing. Ard Tijsterman (Managing Director) explains that during the SURE Cell Line development program™ of Selexis S.A., process development activities are in parallel started with the lead clones at the Xendo laboratories. At this point, the high level Regulatory and QA compliance expertise is included in the project to make sure the development phase results in a fully scalable cGMP compliant process, suitable for manufacturing of pre-clinical and phase I clinical material. This can be extended with a complete phase I submission package for the regulatory authorities and even combined with the clinical testing at Xendo's in house CRO group. Xendo Manufacturing B.V. applies a disposable manufacturing strategy, specifically developed for the transfected CHO and HEK cell lines of Selexis.

Selexis CEO, Dr. Igor Fisch, stipulates the importance of this cooperation since it is now possible to bring a lead candidate cDNA sequence in a genetically stable host to the clinic in a 14-18 month timeframe. The integration of the established Selexis SURE Cell Line Development<sup>SM</sup> program™ for CHO and HEK with the standardized scale up strategy and Xendo's advanced consultancy and manufacturing services provides the biopharmaceutical industry the opportunity to reach the proof of principle stage at least 4 – 6 months faster in a more cost effective manner. This is a total program management solution.

Both companies are convinced that this concept is attractive both for Biotech start ups who lack the complete infrastructure for drug development as well as for the mid size and large pharma companies who want to accelerate their projects in the product pipeline.

***Company descriptions & contact information;***

**Xendo** is a Dutch privately held, independent consultancy, contract research and contract manufacturing organization in the life sciences, pharmaceutical and healthcare fields. It is Xendo's ambition to enhance the quality and safety of medicines and help shorten the time to market for drugs and medical devices that improve the quality of life.

Xendo B.V.,  
Bio Science Park, Archimedesweg 17, 2333 CM Leiden, The Netherlands  
Phone +31 (0)71 524 40 00  
Email: [Ard.Tijsterman@Xendo.com](mailto:Ard.Tijsterman@Xendo.com)  
Website: [www.xendo.com](http://www.xendo.com)

**Selexis** is a Swiss based, privately held biotechnology company dedicated to the development of innovative technologies and expert services that enables significant improvements in the time, effort and costs required to develop and maintain high-performance mammalian cell lines used in the expression of pharmaceutically relevant proteins (i.e. targets, MABs, rProteins). The company's core intellectual property portfolio is based on the discovery and application of epigenetic DNA based elements (Selexis Genetic Elements™) that control the dynamic organization of chromatin within all mammalian cells. Application of the Selexis Genetic Elements™ and Selexis SUREtech Vectors™ using the Selexis SURE Cell Line

Development<sup>SM</sup> process have enabled the rapid development of high performance cell lines for a number of pharmaceutically important clinical programs.

Selexis S.A.  
18, chem des Aulx  
1228 Plan-les-Outes, Switzerland  
Phone +41 (0) 22 308 9360  
Email: [andrew.sandford@selexis.com](mailto:andrew.sandford@selexis.com)  
Website: [www.selexis.com](http://www.selexis.com)