Commercialisation of RUCONEST® in Europe

The roll-out of RUCONEST® in Europe is progressing, although gaining market access across Europe has generally been slower than Pharming initially expected, reflecting the process of obtaining national, regional and local listings and reimbursements, getting labelling improvements approved by the EMA and developing real competition with existing market participants (this is a challenge faced by the entire industry and is not unique to Pharming). Nonetheless, the Company anticipates that RUCONEST® will be properly available and competitive in all of the major European markets by the end of 2017.

Pharming's business model depends on commercial partners to market its product in the various territories where it does not have commercialisation rights or where it does not have the necessary market access and expertise. Pharming is also indirectly exposed to the risks of its chosen partners. The Company continues to believe that RUCONEST® is a very valuable addition to the therapeutic options available to HAE patients and Pharming continues to support its commercialisation partners in their endeavours.

Research & Development

Pipeline

On 18 July 2016, Pharming announced positive results from a Phase II clinical study of RUCONEST® for prophylaxis in patients with HAE. In the study, RUCONEST® showed a clinically relevant and statistically significant reduction in attack frequency for both the twice-weekly and once-weekly treatment regimens as compared with placebo. Pharming will schedule a meeting with the FDA early next year to discuss the parameters for the ongoing clinical development of RUCONEST® in prophylaxis of HAE with the FDA. The Company expects that any further clinical development in this study program (Study 3201) will be completed by the end of 2018 at the latest, enabling a new application for a BLA with the FDA in prophylaxis to be filed soon after such studies are complete, assuming that the necessary endpoints are achieved.

The other programs of Pharming have all passed the lead optimalisation phase during which the lead drug molecule is improved and perfected. These programs are now in pre-clinical stage as is shown in the picture below. The last three programs are further discussed in the following paragraphs.