Troikaa is looking for licensing partner in EU

Sohini Das - Ahmedabad June 2

Has roped in Quintiles for conducting clinical trials for EU

As Ahmedabad-based mid-sized pharma player Troikaa Pharmaceuticals plans to spread its wings to the European Union (EU) nations with its flagship product Dynapar AQ, it has roped in global clinical research organisation Quintiles to conduct the trials required for the regulatory approvals. Going forward, Troikaa is mulling to scout for an out-licensing partner who will market the drug in these countries.

The company is betting big on the product, a diclofenac or painkiller injection, that helped it win a national research and development (R&D) award from the department of science and industrial research, Union ministry of science and technology earlier this month.

"We have roped in Quintiles to conduct the clinical trials that will enable us to get the regulatory approvals for entering the EU market. Usually, once the results of the global clinical trials come in, they are valid for all the regulated markets including EU, Canada, Australia, New Zealand and Japan. For the US Food and Drugs Administration (USFDA), we would need to conduct fresh round of trials.", Ketan Patel, managing director, Troikaa Pharma adding that it might take two to three years time before the company can enter the EU markets.

The net expenses on the clinical trials and subsequent procedural formalities to enter individual countries would be roughly between Rs 7-10 crore, Patel informed. Going forward, the company is planning to associate with an out-licensing partner who will market Dynapar AQ in these markets. "We can tie up with a player who is already operating in these markets, who can, in turn, market Dynapar AQ. This can be a cost-effective measure," Patel said.

Explaining the details of a potential licensing deal, he said, "There can be several kinds of licensing agreements. We can sell our intellectual property rights (IPR) to the company who can manufacture it on our behalf and market under its own brand. There can be a one-time payment plus royalty option. Otherwise, we can also manufacture the product in India, as it is cost efficient, and the licensing partner can market it."

Patel, however, mentioned that it is important to first get the approvals in place, as that would fetch favourable licensing deals for the company in the future. Troikaa had started off with exporting Dynapar AQ, to the Commonwealth of Independent States or CIS countries include Ukraine, Kazakhastan, Belarus, Uzbekistan, Turkmenistan, Kyrgystan, Russia among others and the African block. It has a 28 per cent share in the domestic market, where it sells the product priced at a slight premium compared to its closest competitor Novartis. "We charge a slight premium of Re 1 per dose as we have developed a patented technology or novel drug delivery system.", Patel said.

As for its US plans, the company will launch it priced around $ 2 per dose. Diclofenac injections are not used in the US now,which uses Kitorolac in place of Diclofenac. If things work out then Troikaa would be the first company to introduce the product in the US.