AqVida joins European generics pioneers with Sunitinib development

Press Release | AqVida GmbH

AUGUST 13, 2015

Hamburg, Germany: – Innovative North German oncology laboratory AqVida has joined the first wave of European generics producers with its development of Sunitinib as a generic version of the Sutent® tyrosine kinase inhibitor. The company now says it expects to complete Sunitinib development by end 2015.

AqVida will thus become one of the first companies to apply for a generic version in Europe ready to make application as soon as the Data Expiry Period (DEP) earliest legal date to apply a generic version on July 19, 2016.

It will seek marketing approval (MA) for Sunitinib in several EU territories and will be able to offer speed to market for Sunitinib capsules now in advanced development, ready for 2021/2022 Sutent® patent expiry in most European countries and immediate capability to supply non-infringing markets where no patent applies.

Patent-free zone

AqVida will be able to support commercial scale production with the key marketing advantage of all active pharmaceutical ingredients (APIs) and finished dosage forms (FDFs) being manufactured in patent-free zones. AqVida is specialized and fully dedicated to development manufacturing and licensing of oncology FDFs.
“Our development phase, with a supply chain including backward integrated APIs, has been running very smoothly and so we are confident in being able to meet all our project timelines,” said Dr. Stephan Zinzen, Head of Product Development.

“As soon as the Sutent® patent comes off, we will be able to provide product with at least three years stability,” said Dr. Zinzen.

Fast market

“AqVida is now ready willing and able to enter licensing deals for Sunitinib with deals that can be signed right now,” said Commercial Director Jürgen Lehmberg.

AqVida will capitalize on its distinctive ‘fast market’ offer with spare European licenses on offer for immediate transfer on its core portfolio of injectables. AqVida will also be able to offer first class regulatory services by a team with significant experience.

The company has already successfully developed a previous tyrosine kinase inhibitor, Imatinib, and Mr. Lehmberg revealed the company was planning further developments in this product category.

AqVida is fully dedicated and specialized in development, manufacturing and licensing of onco generics.

Celebrating its tenth anniversary this year, AqVida has been growing rapidly in recent years, with new capacity shortly to come on stream from a new injectables manufacturing site close to Hamburg in Germany. Using robotic filling technology in an isolator, this new site is novel in the oncology field, is innovative, supports and improves AqVida’s flexibilty significantly. Applying a new 100% weight accurate filling process for different vial sizes and formats (2R – 100 H), the new site is considered a *“Zero Loss Facility”*, which makes it attractive especially for high value products in the field of oncology, including e.g. ADCs (Antibody Drug Conjugates)

About AqVida

AqVida GmbH is a German pharmaceutical company specializing in the fast-track development registration and distribution of finished dosage forms mainly in the oncology sector. It has developed a portfolio of medicines for treating the most common types of cancer.

AqVida’s expertise in the development, registration and supply of generic oncology products and biosimilars has made the company a leading partner in the pharmaceutical industry. The Hamburg-based company also has offices in Oberhaching, Bavaria and in Hangzhou, China.

AqVida works alongside some of the major companies in the market of oncology products. Together with its partners AqVida has achieved substantial development and growth with its oncology portfolio.

After having developed and launched several oncology parenteral forms such as e.g. Paclitaxel, Docetaxel and Oxaliplatin, AqVida and its partner company, Benavis, started development work on the ‘tinib’ series of molecular targeted anti-cancer molecules. AqVida is also developing other molecular targeted anti-cancer molecules, such as Sunitinib.

Products are sold under the AqVida brand or those of its partners’ in the EU and other markets.

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Resources

Click on AqVida joins European generics pioneers with Sunitinib development for other information.
Click on AqVida to contact the company directly.

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