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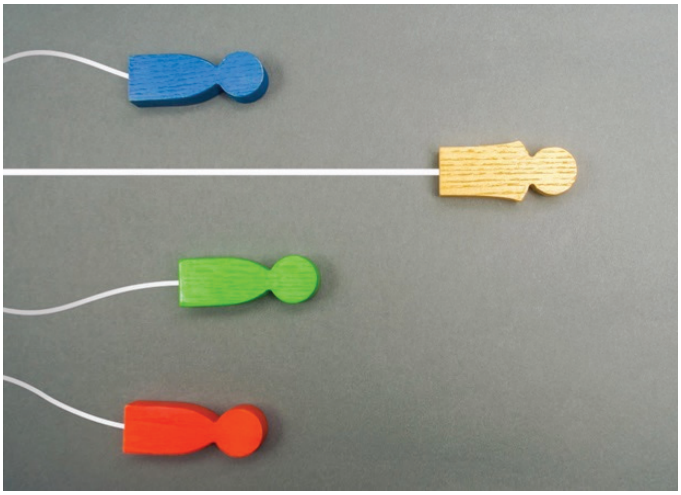
By David Wallace



MALTA-BASED GENERICS DEVELOPER AND MANUFACTURER PHARMACARE Premium believes it is leading the way on developing a generic pazopanib rival to Novartis' Votrient cancer treatment for the European market.

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Malta-based B2B generics developer and manufacturer Pharmacare Premium has claimed a leading position in developing a generic rival to Novartis' Votrient (pazopanib) for the European market after completing key bioequivalence trials for the oncology drug.

Having begun developing generics just three years ago – and having since "successfully completed some co-development projects" – the specialist in high-potency oral solid dosage forms told Generics Bulletin that it had just successfully completed two bioequivalence studies for a generic version of pazopanib that was internally developed by Pharmacare and for which it is now compiling an EU dossier.

The successful studies for both the 200mg and 400mg strengths – matching the Votrient brand – were particularly notable, the company said, given the "very limited number of successes with this product."

Development of pazopanib was "complicated, due to the characteristics of the innovator's product and complexity of finding the in-vitro/in-vivo correlations," a Pharmacare spokesperson explained, "in addition to the fact that the two strengths are not linear when it comes to bio-availability, hence requiring two separate bioequivalence studies, one for each strength."

"Due to the above and because of Malta's time advantage in commercialization, we are not aware, to date, of other available generic dossiers by competitors," the company indicated, "apart from one company offering a dossier with only one strength."

According to Novartis, global Votrient sales were $635m in 2020, down 16% from 2019.

Asked about a potential launch date and intellectual property barriers, Pharmacare said that "major EU launches will be possible upon supplementary protection certificate expiry in June 2025." But "earlier launches in non-SPC countries in the EU, as well as Rest of World territories, can start as early as December 2021," the company suggested, "with the unique advantage of being able to supply from the EU (Malta) due to Malta's patent advantage."

"We have numerous business partners and look forward to expand this base inside and outside the EU," the company concluded, insisting that along with the "patent advantage" of its Malta base and manufacturing facility, it could also offer a "very high degree of flexibility in delivery of small quantities typically associated with oncology products and early launches."

"Our development circumvents all secondary patents," the company added, "and the dossier will be filed in Q4 of this year in the EU and by our customers, in addition to agreements being finalized at the moment for Turkey, the Middle East and North Africa region, and Latin America."