CEO Carlo Montagner Discusses Recent Partnership Deal

This article appeared on page 36 in Pharma Asset Insights (a Scrip industry publication). Click on the Fullscreen button in the middle of the magazine below to read it or scroll down to read the article within this webpage.

“Our most recent partnership deal was with US-based Puma Biotechnology (NASDAQ: PBYI).

This novel early breast cancer drug first came to our attention in 2011 when Puma acquired the rights from Pfizer.

Following a successful FDA ODAC hearing in 2017, we reached out to Puma for an initial exploratory discussion on commercialising NERLYNX in our region. Less than 6 months later, we not only struck an exclusive license agreement , but we have submitted the New Drug Application dossier to the Therapeutic Goods Administration (TGA) and have made NERLYNX available to appropriate Australian patients via a strictly-controlled patient access program using our proprietary access program platform.

We were able to move quickly because, as I am the 100% owner and CEO of the company, our internal review and approval processes are not subject to multiple internal senior management and board reviews. This means decision making and post-deal product commercialisation execution can be rapid.

If we make a commitment to filing a dossier on a particular date — subject to external influences beyond our control — we have always achieved that commitment.

We were looking for a drug that fulfilled an unmet need and provided a reasonable commercial opportunity.

NERLYNX overwhelmingly met these criteria. It is the first FDA-approved drug for extended adjuvant therapy in women with early stage HER2+ breast cancer and is clearly not a 'me-too' product.

In this case, due diligence processes were also expedited. Our team is comprised of senior pharma executives with many years of regulatory and commercialisation experience. With NERLYNX, we were able to rapidly assess the commercial opportunity as well as the likelihood of regulatory and reimbursement success.

Once due diligence was completed, negotiations commenced on the license terms.

Like all our agreements, the Puma deal was tailored to meet the needs of our partner. These arrangements need to be customised as our partners all have different requirements and operate in different jurisdictions.

Making NERLYNX available to women prior to TGA approval has required particular commercialisation skill.

In addition to the usual advisory boards and meeting with key stakeholders, ST also launches early access programs to potential prescribers.

These programs ensure our customers become familiar with the product, but more importantly, they enable appropriate access to patients in need at the earliest opportunity.

Our NERLYNX access program was launched in Australia in late March – four months post-deal.

We have developed a rigorous process for managing these access programs pre and post regulatory approval, and are currently operating several simultaneously.

With NERLYNX, we are targeting a reimbursement approval within 18 months of submitting our regulatory dossier.

Again, we have a strong track record of achieving these critical milestones and now look forward to making this important medicine available to appropriate Australian women."