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Sumitomo turns to Tolero to plug patent expiry gap

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2016 is about to come to a close but deals still have to get done, and business development executives and bankers eager for Christmas bonuses will take heart in Japanese groups' willingness to buy into biotech at a premium.

Thus yesterday the private haemato-oncology focused group Tolero sold itself to Sumitomo Dainippon Pharma for $200m, one day after Otsuka rescued Akebia in a licensing deal worth $125m up front. Tolero should enhance Sumitomo's oncology pipeline, but on its own it will not make up for the punishing patent expiry of Latuda, the Japanese group's single most important drug.

At least Sumitomo is showing that it takes the issue seriously: Tolero is its second North American acquisition in the space of three months, coming on the heels of the $624m takeover of Cynapsus Therapeutics, a recently floated Canadian business with a largely derisked asset targeting "off" episodes in Parkinson's disease.

That price looked rich, but then Sumitomo at this point has little choice but to put down big bets. Latuda, a schizophrenia drug, looks set to sell $1.3bn this year – more than half of the company's prescription drug revenues – but after patent exclusivity expires in 2018 the drug's sales are expected to fall to almost nothing.

Since Tolero is private there are no sellside forecasts for its most promising R&D assets. However, the attraction for Sumitomo is clear: Tolero's lead asset is alvocidib, a CDK inhibitor following in the footsteps of Pfizer's blockbuster Ibrance.

However, alvocidib hits CDK 9 while Ibrance, as well as the promising imitators Novartis's ribociclib and Eli Lilly's abemaciclib, target the CDK 4 and 6 subtypes (*Esmo – Novartis finds a little masterpiece in ribociclib breast cancer data*, October 9, 2016). And the fact that alvocidib was originated by Sanofi, which rather than developing it licensed it to Tolero, might also raise eyebrows.

However, the real excitement might lie in Tolero's alvocidib prodrug, TP-1287, which is wholly owned and has potential to be dosed orally rather than IV. While Ibrance and others have initially targeted breast cancer, alvocidib's focus is on the intractable haematological malignancy AML.

Tolero's R&D pipeline		
Project	**Pharmacology class**	**Lead indication(s)**
Phase II		
Alvocidib	CDK 9 inhibitor	Acute myeloid leukaemia
Phase I		
TP-0903	Axl kinase inhibitor	Pancreatic & brian cancers
Preclinical		
TP-1287	Oral CDK 9 inhibitor	Oncology
TP-0184	Alk2 inhibitor	Anaemia of chronic disease
SGI-9481	Pim-1 kinase inhibitor	Prostate cancer & acute myeloid leukaemia
TP-1454	PKM2 activator	Oncology
HCI-1680/HCI-1708	PDK1 inhibitor	Oncology
MKC4659	BTK inhibitor	Oncology
Source: EvaluatePharma and company reports.		

Interestingly, Sumitomo's marketed product offering does not feature cancer drugs, and the group is instead largely focused on central nervous system disorders.

However, its pipeline includes napabucasin, in phase III for lung and gastro-intestinal cancers, and rights to Roche's phase II myelodysplastic syndromes agent WT4869. Among other pharmacological approaches of interest, Tolero is known previously to have been working preclinically on MKC4659 – a BTK inhibitor like Abbvie's Imbruvica – but its current status is unclear.

In addition to the $200m up-front fee Sumitomo stands to pay Tolero's sellers up to $430m in development-based milestones. The Tolero portfolio is still too early to value without a steep discount for risk, but at least the Japanese group is taking multiple shots on goal.

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