

AZ, Pharmacyclics & Janssen partner on immuno-oncology combination trials

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AstraZeneca, Pharmacyclics, Inc. and Janssen Research & Development announced that they have entered into a clinical trial collaboration to evaluate the efficacy and safety of AstraZeneca's investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in combination with IMBRUVICA (ibrutinib), an oral Bruton's tyrosine kinase inhibitor, co-developed by Pharmacyclics and Janssen and commercialised outside the US by Janssen affiliates.

The study will assess the combination as a treatment for patients with haematological cancers including diffuse large B-cell lymphoma and follicular lymphoma, which are investigational uses for both compounds.

The financial terms of the agreement have not been disclosed. MEDI4736 blocks the signals that help tumours avoid detection by the immune system, countering the tumour's immune-evading tactics. Ibrutinib blocks signals that tell malignant B cells (white blood cells that produce antibodies) to multiply and spread uncontrollably. Preclinical evidence suggests that the combination of these two agents may lead to an enhanced anti-tumour immune response.

The Phase I part of the trial is expected to establish a recommended dose regimen for the combination of MEDI4736 and ibrutinib, and the Phase IIa part of the trial will assess the safety and efficacy of the investigational combination. Under the terms of the agreement, the two-part trial will be conducted by Pharmacyclics.

Mr Briggs Morrison, executive VP, global medicines development & chief medical officer, AstraZeneca, said, "We are committed to progressing our strong immuno-oncology pipeline as rapidly as possible. Our partnership with Pharmacyclics and Janssen supports our exploration of the potential of anti-PD-L1 in hematological cancers and is further evidence of our belief that combination therapies have the potential to be one of the most effective ways of treating cancer."

"Cancer drug development is at one of its most exciting, productive periods in history," said Dr Peter Lebowitz, global oncology head, Janssen. "This collaboration reflects the common goal of all three companies to better understand new treatment options and combinations - with the ultimate goal of making a difference to the lives of people with hematologic

malignancies."

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