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ASIA EDITION

Accro and Fosun advance oral TYK2/JAK1 inhibitor AC-201 into China Phase II/III vitiligo trial

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Chinaâ??s NMPA has cleared an adaptive seamless Phase II/III study of the selective oral small-molecule inhibitor for non-segmental vitiligo.

Accro Bioscience and Fosun Pharma are preparing to advance AC-201 into a Phase II/III clinical trial in China for non-segmental vitiligo following regulatory clearance from the National Medical Products Administration.

Shanghai Fosun Pharmaceutical Industrial Development, a subsidiary of Fosun Pharma and partner of Accro Bioscience, has received approval to conduct an adaptive seamless Phase II/III study of AC-201 tablets.

The trial is expected to begin in mainland China once the required conditions are in place.

AC-201, also known under Fosun's development code FXS5626, is a novel oral small-molecule inhibitor targeting TYK2 and JAK1.

The candidate binds to the pseudokinase JH2 domain of TYK2/JAK1 and is designed to achieve high selectivity while exerting minimal activity on JAK2-associated signalling.

The programme is being developed for non-segmental vitiligo, an autoimmune condition characterised by loss of pigment-producing melanocytes and resulting depigmented skin lesions.

JAK signalling has become an increasingly important therapeutic target in inflammatory and autoimmune dermatology as developers seek more targeted approaches to modulating disease-driving immune pathways.

The Phase II/III adaptive seamless design is intended to allow development to progress across clinical stages within an integrated programme.

The regulatory clearance marks another step in the clinical development collaboration between Accro Bioscience and Fosun Pharma.

For Accro, the programme also represents progress in translating its small-molecule immunology platform into later-stage clinical development in China.

The trial will provide further evidence on the safety and efficacy of selective TYK2/JAK1 inhibition in patients with non-segmental vitiligo as the companies assess the candidate’s potential role within an increasingly competitive dermatology treatment landscape.