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Merck launches excipient technology platform for protein-based therapeutics

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New excipient combinations help overcome manufacturing and formulation challenges of highly concentrated protein solutions by viscosity reduction

The Life Science business of Merck has launched a new Viscosity Reduction Excipient Platform to reduce the viscosity and help overcome manufacturing and formulation challenges associated with highly concentrated protein solutions.

The core of the new technology platform is the combination of two new excipients, one amino acid with one anionic component. The use of excipient combinations provides the following synergies:

- Viscosity reduction beyond reduction with single excipients
- Improved balance of viscosity vs. stability

For protein-based therapeutics, such as monoclonal antibodies (mAbs) or plasma-derived proteins, subcutaneous administration is the preferred route of administration as it improves patient compliance. Such formulations often require highly concentrated protein formulations, however, to meet intended dosing regimens. Highly concentrated protein solutions tend to exhibit elevated viscosities, which presents a challenge in the manufacturing process and final formulation.

The synergistic effects of the excipient combinations in the Viscosity Reduction Platform deliver several advantages for formulation including:

- Reducing the viscosity of highly concentrated protein therapeutics including mAbs to enable subcutaneous formulation
- Increasing the concentration of plasma protein-based therapeutics
- Improving the ability to handle high concentration formulations in downstream processing
- Enabling competitive differentiation via protected intellectual property and technology licensing

All the excipient candidates have been previously used individually in approved drug products for humans via parenteral administration, for example as active ingredients in parenteral nutrition or as pH adjusters. The excipients will be subsequently made available in Emprove® Expert quality, supporting the described new excipient application.