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HRV Pharma and Haleos Labs forge strategic CDMO alliance to fast-track orphan drug & niche API development

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HRV Global Life Sciences (HRV Pharma) has announced a comprehensive, multi-year strategic development partnership with SMS LifeSciences (now Haleos Labs).

This exclusive partnership focuses on the development, scale-up and GMP manufacturing of multiple orphan-drug and niche-therapeutic APIs for regulated & semi-regulated markets. The collaboration brings together HRV's world-wide market access, commercial footprint across 50+ countries, and its digital, asset-light Virtual API platform, with SMS's deep chemistry capabilities, WHO-GMP aligned manufacturing systems, and proven track record in specialty API production.

Under the agreement, both companies will jointly execute:

- Co-development of a multi-year pipeline of high-value specialty APIs, including orphan, ultra-rare and niche-therapeutic categories
- End-to-end GMP development and commercial manufacturing — from route scouting and process intensification to scale-up, validation and global supply
- Integrated global regulatory strategy, including DMF filings across US, EU, LATAM, MENA & APAC supported by complete CMC, stability, validation and technical documentation
- A forward-looking annual launch program, introducing 5–7 new molecules every year across rare diseases, CNS disorders, metabolic conditions and high-science therapeutic spaces
- A harmonised quality, compliance and audit-readiness framework, engineered to meet the stringent expectations of USFDA, EMA, PMDA, ANVISA and other regulatory authorities

The partnership has already launched with a structured pipeline of five initial orphan/niche therapeutic programmes, with additional molecules planned each year under a unified annual development framework. Multiple US DMF’s have already been filed by HRV Pharma as a result of fledging partnership between the two organizations.

Both organisations will jointly manage CMC documentation, stability studies, validation programmes and global regulatory interactions, creating a seamless development-to-commercialisation pathway.