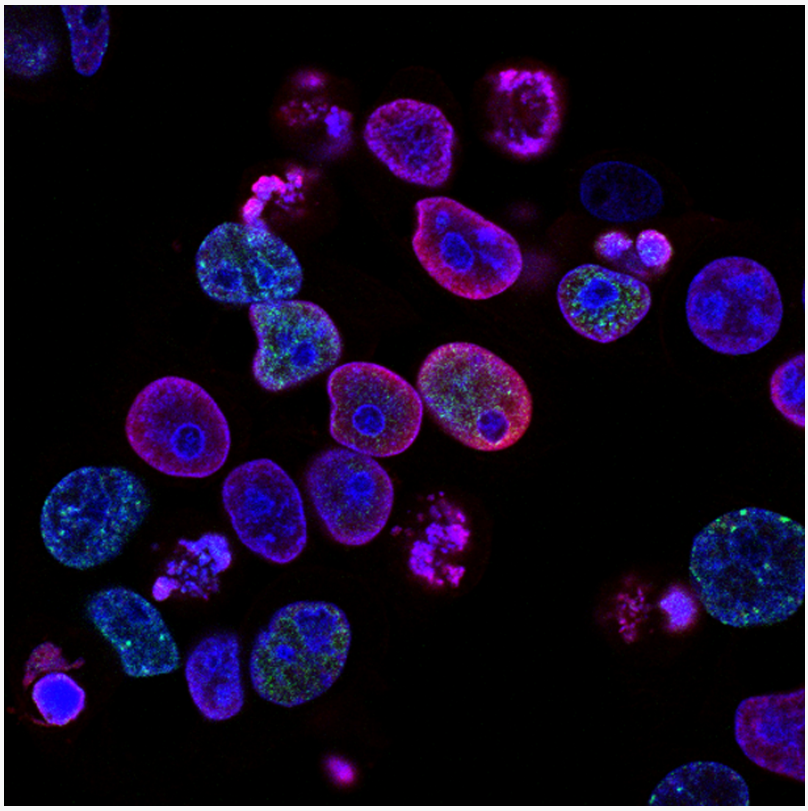
Clinscience and Ryvu Therapeutics sign two Agreements for RVU120

Clinscience and Ryvu Therapeutics sign Data Management and Biostatistics Agreement for RVU120 Phase II Clinical Trials in Hematology



WARSAW, POLAND, August 29, 2023 /EINPresswire.com/ -- Clinscience, an oncology focused boutique CRO with hubs across Europe, the United States and India, has partnered with Ryvu Therapeutics to support the development of RVU120. The organizations will work together on the RIVER-52 and RIVER-81 clinical studies with Clinscience providing data operations and statistical support-related services.

Both studies aim to advance RVU120 in Phase II clinical trials, either as a monotherapy or in combination with venetoclax for the treatment of patients with Acute Myeloid Leukemia (AML) or High-Risk Myelodysplastic Syndrome (HR-MDS). Ryvu assumes the possible fast-to-market strategy for the RIVER-52 study, with a potential initiation of the drug registration process in 2025.
Clinscience has been particularly built to serve biotech companies such as Ryvu thanks to our hemato-oncology expertise, technical excellence, global footprint and commitment to excellence.

Krystyna Kowalczyk, CEO of Clinscience, commented:
"Clinscience is thrilled to partner with Ryvu Therapeutics to support the further clinical development of Ryvu's most advanced fully-owned program – RVU120. Our scientific and technical expertise, specifically in oncology, is perfectly aligned to assist in optimizing the needs of this program. We embrace the opportunity to join forces with Ryvu Therapeutics to improve the lives of cancer patients."

Dr. Kamil Sitarz, a Member of the Management Board and COO of Ryvu Therapeutics, stated:

> Clinscience is thrilled to partner with Ryvu Therapeutics to support the further clinical development of Ryvu's most advanced fully-owned program – RVU120."
>
> *Krystyna Kowalczyk*

"We are working intensively on the initiation of Phase II clinical trials for RVU120 in several therapeutic areas. We carefully select service providers to ensure cost-effectiveness for Ryvu while maintaining the necessary service quality, flexibility, and risk management capabilities"

"Collaboration with Clinscience in the area of clinical data management and biostatistics will provide us with high-quality, comprehensive solutions tailored specifically to our needs. This collaboration represents another step towards the dynamic development of RVU120 in Phase II clinical trials in the hematological field."

RVU120 is a selective, first-in-class dual CDK8/CDK19 kinase inhibitor that has shown signs of clinical activity in treated patients, as well as efficacy in numerous in vitro and in vivo models of hematologic malignancies and solid tumors. Results from the ongoing RVU120 study in AML/HR-MDS have shown a favorable safety profile and clinical benefit in 11 out of 24 evaluable patients (dose up to 135 mg, data cut-off on May 25).

Venetoclax is a BCL-2 inhibitor that is approved in combination with a hypomethylating agent for the treatment of newly diagnosed AML in patients that are unfit to receive intensive induction chemotherapy. Its use has been widely adopted in the treatment paradigm. In the non-clinical studies, RVU120 was synergistic with venetoclax in both venetoclax-sensitive and venetoclax-resistant models.

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