

## PRESS RELEASE

### **CEVEC's license partner RZNOMICS Inc. receives approval to initiate clinical development of CAP<sup>®</sup> Ad Technology-produced gene therapy vector in liver cancer patients**

- **RZNOMICS uses CEVEC's CAP<sup>®</sup> Ad viral vector manufacturing technology for manufacturing gene therapy vectors targeting various cancer indications**
- **South Korean Ministry of Food and Drug Safety granted IND approval for a clinical phase 1/2a trial to evaluate safety and efficacy of RZNOMICS lead gene therapy RZ001 for the treatment of primary liver cancer**
- **Another important milestone has been reached for CEVEC's unique CAP<sup>®</sup> cell line which enables by design the efficient production of high-quality, RCA-free adenoviral vectors**

**Cologne, Germany, July 13<sup>th</sup>, 2022**

CEVEC Pharmaceuticals GmbH (CEVEC) today announced that an important milestone in the partnership with RZNOMICS, Inc. (RZNOMICS) was achieved when the South Korean Ministry of Food and Drug Safety granted IND (Investigational New Drug) approval to initiate a phase 1/2a clinical trial with RZNOMICS' lead candidate RZ001. RZ001, a gene therapy based on the company's proprietary trans-splicing ribozyme technology and being developed for the treatment of primary liver cancer, uses CEVEC's CAP<sup>®</sup> Ad Technology to manufacture RCA-free adenoviral vectors for the efficient and safe drug delivery to the target cells. With this regulatory clearance, RZNOMICS plans to submit an IND to the U.S. Food and Drug Administration (FDA) in the second half of this year.

"We are delighted to see RZNOMICS advance its lead compound, a gene therapy produced using our CAP<sup>®</sup> Ad Technology, into clinical development," said **Dr. Nicole Faust, CEO of CEVEC**. "By providing a unique technology that enables the manufacturing of safe adenoviral vectors by eliminating the generation of replication competent adenovirus (RCA), we help our partners to address one of the major challenges in adenovirus-based gene therapy and vaccine production. We look forward to continuing the work with RZNOMICS and supporting them through clinical development and further onto the market."

"This is a monumental achievement of administering a therapeutic substance using ribonucleic acid splicing enzyme technology to patients with primary liver cancer for the first time in the world", said **Seong-Wook Lee, Ph.D., CEO of RZNOMICS**. "The advantages of the CAP<sup>®</sup> Ad Technology in terms of safety and scale up convinced us to select it as the technology to produce our gene therapy candidate based on adenoviral vector for the clinical purpose", he added.

In 2020, CEVEC and RZNOMICS signed a license agreement for the use of CEVEC's CAP<sup>®</sup> Ad Technology for manufacturing of adenoviral vectors in combination with RZNOMICS' proprietary development portfolio of gene therapies targeting various cancer indications.

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### About CAP® Ad Technology

The CAP® Ad Technology is an innovative technology platform developed by CEVEC for the scalable production of RCA-free adenoviral vectors for gene therapy applications and vaccines.

Recombinant adenoviral vectors are among the most efficient vectors for gene therapy purposes and have become the vehicle of choice in many human gene therapies. Today, many cell lines used for production of adenoviral vectors generate certain levels of replication-competent adenovirus (RCA). The presence of RCA in adenoviral vector preparations which are intended for use in humans is increasingly considered to be a potential risk, especially for immuno-compromised patients. The CAP® cell line is specifically designed to avoid the production of RCA.

CEVEC's CAP® cell line is based on an engineered human suspension cell line of non-tumor origin, derived from human amniocytes. CAP® cells can be grown in all formats and all sizes of bioreactors, providing a robust, fully scalable production platform for the manufacturing of adenoviral vectors from research grade and smaller amounts up to industrial volumes. The CAP® cell line has been fully documented and reviewed by regulatory authorities. Since 2016, a Biologics Master File has been available for reference with the U.S. FDA. GMP Master Cell Banks are available and ready for licensing.

### About CEVEC

CEVEC is a leading provider of high-performance cell technology for the manufacturing of advanced biotherapeutics.

With the **ELEVECTA® Technology**, CEVEC offers a unique solution for large-scale production of AAV vectors using helper virus-free inducible producer cell lines with all necessary components stably integrated into the cell. The technology is based on suspension cells and does not require any expensive transfection reagents nor cGMP plasmids. **CEVEC's CAP® Ad Technology** is the ideal production platform for RCA-free adenoviral vectors. Based on human suspension cells, it allows for a robust manufacturing process, easy scale-up from research grade to industrial volumes and thus opens the way for various applications, from gene therapy to vaccine production.

### About Rznomics:

**Rznomics** is a biopharmaceutical company founded in 2017 dedicated to the development of gene therapies for cancers, degenerative diseases, and genetic diseases based on cutting-edge RNA technology. Core platform technology of Rznomics is based on RNA replacement enzyme called '**trans-splicing ribozyme**', which can edit target RNAs through simultaneous destruction and repair (and/or reprogramming) to yield the desired therapeutic RNAs, thus selectively inducing therapeutic gene activity in cells expressing the target RNAs. Rznomics has developed and optimized the ribozymes to be applied as therapeutics for intractable human disease by developing them to have high target specificity and efficacy, target accuracy, and minimal off-target ability. Rznomics has established pipelines targeting indications with high unmet medical demand for which the unique properties of

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the ribozymes can be the most competitive. The leading candidate is treatment for hepatocellular carcinoma, and treatments for glioblastoma, Alzheimer's disease and hereditary retinal dystrophy are also under development. For more information, please visit [www.rznomics.com](http://www.rznomics.com).

For more information, please visit our [website](#).  
Follow CEVEC on [LinkedIn](#) and [Twitter](#).

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