Press Release

Informa 2018 Survey predicts Drug Product Formulation Recognition and Budgets to increase significantly

- **Formulation issues cause significant drug project delays and project failures, as experienced by 60% of survey participants.**
- **Majority experienced clinical development delays by more than 12 months and 10% experienced a complete failure due to formulation issues.**
- **Mean average doubling of investments on formulation per project over the next five years anticipated.**
- **Importance of early-stage formulation currently underestimated.**

Laupheim, Germany, and Munich/Martinsried, Germany, November 6, 2018 – Rentschler Biopharma SE and LEUKOCARE AG today reported results from their joint publication of the 2018 Survey '*Formulation in the Drug Product Development Process*', based on research from Informa Pharma Intelligence. In addition to the findings presented here, the complete report will be available for download after November 6, 2018, 16:15 via this link: https://www.rentschler-biopharma.com/fileadmin/user_upload/News/Downloads/20181106_Full_report_for_release.pdf.

Formulation issues have led to the failure of drug development projects or significant delays for about 60% of companies responding to the industry survey, making formulation a key aspect in drug development. This was just one important fact revealed by the 2018 Survey '*Formulation in the Drug Product Development Process*' that has been published today. The survey was conducted by Rentschler Biopharma, LEUKOCARE and Informa Pharma Intelligence among biotech and pharma companies, worldwide. It was completed by 150 respondents active in the biopharmaceutical and / or vaccine industry.

Importance of early-stage formulation currently underestimated

One important finding was that, of the projects which were delayed or failed due to formulation challenges, a project delay of over 12 months was reported by more than 50% of the respondents while 10% of respondents experienced the complete failure of a project.

"Given this very obvious and significant impact on the success of drug development, we were surprised to see that about half of all respondents thought the deployment of a 'commercially viable' formulation should take place only during or after Phase IIa clinical trials or as late as the start of Phase III trials," noted Michael Scholl, CEO of LEUKOCARE.

"There are many opportunities that can be realized if formulation is properly considered in early drug product development and an optimized formulation is developed. For example, amendments such as longer shelf life, advantages in intellectual property, accelerated market entry and most certainly reduced costs are vital considerations to the success of a drug," added Dr. Frank Mathias, CEO of Rentschler Biopharma.

When asked about important aspects of formulation, 83% of respondents attributed ‘competitive advantage’ as ‘very important or important’ on a five-point scale and 75% found a ‘reduced time to market’ ‘very important or important’.

“The competitive advantages to be gained from strategic formulation planning are potentially vast. For instance, a vaccine that must be transported in cold store or frozen becomes expensive and bulky to transport, while a vaccine that can simply be transported at 4°C or room temperature is relatively inexpensive and the potential geographical markets are much greater,” said Scholl. “Another area of formulation is the ease of use. Intravenous (i.v.) is good to use in hospitals with trained administrators, yet, expensive and very inconvenient both for patients and physicians. Subcutaneous (s.c.) administration gives enormous flexibility and the potential for self-administration in treatments of chronic diseases. Last but not least an improved safety profile of a biologic via i.v. to s.c. switch may add enormous value to patients and pharma.”

Investment in early stage formulation set to increase

In terms of early stage formulation, the responses show a willingness to invest more funds in early stage formulation within the next five years, as indicated by a 3-fold increase of companies planning to spend between US$1 to US$5+ million on formulation per project over the next five years.

“We found that the industry is expecting an approximate mean average doubling of investments. This does indicate that companies are beginning to understand the real potential of drug product formulation. However, the question remains if the current spending on formulation is adequate given the importance that respondents allocate to formulation,” Mathias said. “The indicated raise could also be related to the growth of biosimilar and generic drugs which our clients expect and where they feel a higher investment will put them in a much better competitive position in terms of early market entry, competitive pricing and ease-of-use, for instance.” This view is backed by the survey where IP, time to market and development time topped the respondents’ formulation priorities in response to the question: ‘How important are the following considerations in evaluation of your formulation strategies?’

It became clear that commercial aspects need to be considered when evaluating a formulation strategy but, surprisingly, this is not reflected in the ‘departments included in the formulation decision making process’. Looking at the data, commercialization specialists such as business development, management, along with marketing and sales, seem to be involved to a much lesser extent at the earlier stages of decision making. Whereas, formulation development, bioprocess, drug product development and clinical development are the main decision-making departments at the earlier stages of drug product development.

“It appears there are many different understandings of formulation and the potential it delivers in overcoming drug development challenges. For instance, the costs of putting clinical trials on hold for reasons of formulation are significant and often put massive pressure and risk on R&D budgets,” noted Scholl. “Beyond this, to know the final market positioning of approved products from an early stage can help companies in business development and licensing deals, as well as IP positioning. This study has raised several vital points for the formulation and drug manufacturing industries and we are ready to take these lessons forward in our business,” Mathias added.

The Rentschler Biopharma and LEUKOCARE alliance offers a whole range of services for the drug product development industry and specialist formulation expertise. The alliance aims to incorporate formulation development at every step throughout biopharmaceutical development and manufacturing, especially during the early stages. Working closely with the client, this ensures the end products will – from the very beginning – have a best-in-class formulation and administration mode. This innovative approach provides clients with significant competitive advantages, enabling them to exploit the full commercial potential of their products and markets.

To investigate and challenge the survey report a roundtable discussion will be launched during BIO-Europe® on **Tuesday, November 6th, 2018 from 3:15 p.m. to 4:15 p.m. CET at the Bella Center in Copenhagen**, Denmark. During the session **'A strategic view: Formulation in the drug product development process'** which will be moderated by Mike Ward, Head of Content at Informa Pharma Intelligence Insights, the findings of the survey will be presented and are open for discussion with the panelists and all visitors of BIO-Europe®.

About Rentschler Biopharma SE
Rentschler Biopharma SE, located in Laupheim, Germany, is a leading contract development and manufacturing organization (CDMO), focused exclusively on clients' projects. Rentschler Biopharma offers process development and manufacturing of biopharmaceuticals as well as related consulting activities, including project management and regulatory support. Rentschler Biopharma's high quality is proven by its long-standing experience and excellence as a solution partner for its clients. A high-level quality management system, a well-established operational excellence philosophy and advanced technologies ensure product quality and productivity at each development and manufacturing step. In order to offer optimal solutions across the entire value chain, the company has entered into a strategic alliance for formulation development with Leukocare AG and into a strategic partnership for fill & finish with Rentschler Fill Solutions GmbH. Rentschler Biopharma is a family-owned company employing more than 850 people. For further information, please visit www.rentschler-biopharma.com.

About LEUKOCARE AG
LEUKOCARE AG provides a next-generation formulation platform for the protection of proteins like biopharmaceuticals to allow the development of better products. The proprietary Stabilizing and Protecting Solutions (SPS®) technologies are provided to development projects of partners in the pharmaceutical and medical device industry. LEUKOCARE's SPS® technologies improve stability and quality of biologics like antibodies, viral vectors, vaccines, etc. in dry and liquid formulation including high-concentration formulations. SPS® technologies also protect proteins in biologically functionalized combination devices. For further information, please visit www.leukocare.com.

About the Rentschler Biopharma and LEUKOCARE alliance
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