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FOR IMMEDIATE RELEASE

CASSS ANNOUNCES AVAILABILITY OF A-MAB CASE STUDY

Working with the CMC-Biotech working group to promote and disseminate the A-Mab Case Study is a core fit with the Society's mission to promote discussions among industry, academic and regulatory professionals on the development and applications of separation science. The case study provides many illustrative, sometimes controversial, examples of ways to implement QbD and will stimulate discussion about how the science supports these examples and how we can enhance future biotechnology product realization.

Emeryville, CA – November 5, 2009 -- CASSS – An International Separation Science Society announced the availability today of a case study on the development of a monoclonal antibody. The study represents the culmination of a two-year effort by a consortium of biotechnology companies including Abbott, Amgen, Genentech, GlaxoSmithKline, Lilly, MedImmune and Pfizer. The consortium, collectively known as the CMC-Biotech Working Group, has provided the A-Mab case study to CASSS to ensure free public access and further promote the industry-wide discussions that led to its creation.

"We are pleased to have the opportunity to work with the CMC-Biotech Working Group to promote and disseminate the A-Mab case study," said CASSS Executive Director Stephanie Flores. "With its and its novel ideas and aspirational approaches to Quality by Design, this marks a significant opportunity to facilitate the discussion in the biotechnology community on the implementation of the advanced concepts of QbD. We will highlight the case study on our web site, and we have plans to use it extensively around the world in discussions with industry and regulators throughout 2010 and beyond."

The CMC-BWG consortium comprises some 40 members from seven companies (Abbott, Amgen, Genentech, GlaxoSmithKline, Lilly, Medimmune, and Pfizer) and was established in 2008 to develop a case study illustrating how the principles of Quality by Design (QbD) can be applied to the development of biotechnology products, focusing on monoclonal antibodies. The A-Mab case study discusses the development of a monoclonal antibody and incorporates many advanced and aspirational QbD concepts.

A link to the full text of the A-Mab Case Study is available at:
<http://www.casss.org/displaycommon.cfm?an=1&subarticlenbr=286>

About CASSS

Headquartered in Emeryville, California, CASSS (formerly the California Separation Science Society) is a non-profit professional membership society made up of over 4,000 industry, academic and public sector professionals in the field of separation science.

CASSS is governed by a volunteer board of directors and accomplishes its objectives of providing excellent networking opportunities and high-quality scientific symposia through the dedication and work of a large pool of volunteers who contribute their time and talents as a way of giving back to and improving the field of separation science.

Rewards of active participation in CASSS include great networking opportunities, career advancement and access to outstanding scientific symposia.

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