Antibody drug conjugates (ADCs) combine the specificity of Monoclonal antibodies (mAbs) with the potency of cytotoxic molecules. Along with the development of the mAbs and cytotoxins, the design of chemical linkers to covalently bind these building blocks is making rapid progress but remains challenging.

Lonza offers superior services for your antibody drug conjugates. Take advantage of the best characteristics of mAbs and cytotoxic molecules with Lonza’s Easy Access ADC programs.

**Flexible early clinical development and manufacturing programs**

- Expertise with leading ADC platforms
- Preparation of ADC sample panels using a variety of linker/drug/mAb combinations
- New linker technologies
- R&D safety labs for process development and/or toxicity batches (5mg-40g)
- GMP suites for clinical supply (50-150g)
- Dedicated ADC R&D teams ready for new projects and drop-ins
- R&D projects can start just 2 weeks from a PO
- Toxicology batches can start just 4 weeks from PO in R&D lab, and as little as 6 weeks in GMP suites
- Phase I GMP batch starts: within 8 weeks of PO
- Over 60 GMP clinical ADC batches released w/ batch success rate >95%
ADC Analytical Services

- Complete analytical development packages with mAb/ADC harmonization
- Bioassay implementation
- ADC BDS/DP release and stability testing
- Dedicated ADC QC teams to support new method development or method transfers
- Cross training between chemical and biological analytical groups
- 40 ADC methods developed, implemented and validated to date
- Validated cleaning methods for multiple toxins

Supply chain management and integration

- GS™ Cell Line Construction (CLC) and Monoclonal antibody (mAb) supply via Lonza
- Supply of cytotoxins by Lonza (fermentation and chemical synthesis)
- 200-1000L GMP mAb capacity for early phase
- 200-20,000L GMP mAb capacity for late phase
- Cytotoxins from 10 to 630L in dedicated, segregated clean rooms
- Cross-site Program Management harmonization
- Multiple projects combining mAb/ADC/toxin supply
- Seamless pre-clinical to commercial offering
- mAb and ADC BDS fill options from 1 L bottles to large cryovessels
- Purified solvent for toxin dissolution with detection method
- Cold storage management of BDS
- On site liquid/solid waste incineration (Lonza Visp)

Process scale-up and validation

- Cost of goods (COGs) management
- Process qualification / characterization and scale down modeling
- ADC analytical method validation
- State-of-the-art late stage /commercial SafeBridge certified manufacturing facility
- 100-600L scale SS reaction vessels
- Risk sharing approach to batch success rate

SHE, quality and regulatory expertise

- FDA approved biologics and chemistry site (Lonza Visp)
- Professional safety risk assessment protocol for each project
- Rigorous SHE policy promotes worker and product safety
- CMC support for BLA filings in multiple countries
- Toxin cleaning methods and MAC support for product changeover

To order ADC Sample Preparation Services visit: www.lonza.com/adc
www.lonza.com

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