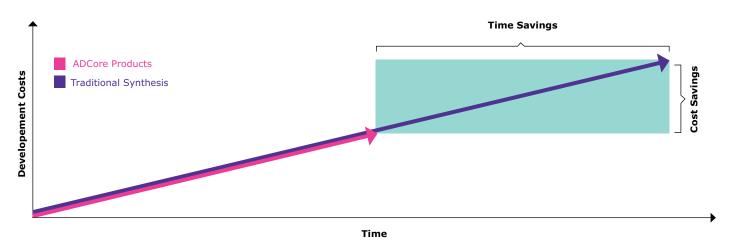


# A New Generation of Advanced Payload Intermediates

# **Reduce Developement Costs and Time with ADCore**



# **Customizable, Off-the-Shelf Intermediates**

Introducing ADCore, a comprehensive product line of advanced intermediates aimed at significantly reducing the time, risks, and challenges associated with ADC payload development and manufacturing.

We offer advanced intermediates for the most common payload classes:

- Dolastatins
- Pyrrolobenzodiazepines (PBDs)
- Maytansinoids

# **Expedite Your ADC Development**

After selecting a clinical candidate, customers must develop numerous steps in-house or at a CDMO to arrive at a suitable GMP payload for use in clinical programs, leading to possible increased costs and delayed timelines. Our ADCore product line aims to address these challenges.

- DOLCore™ Intermediate
- PBDCore™ Intermediate
- MAYCore™ Intermediate

Select the right ADCore product to fit your payload synthesis needs and perform downstream development work in-house or employ our CDMO services to take full advantage of our comprehensive ADC services throughout all stages of drug development and manufacture.

#### **Product Features**

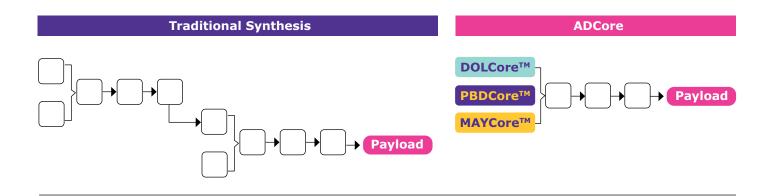
- Samples offered free of charge
- Full regulatory support
- · No royalties or licensing fees
- · High purity material
- Suitable for up to phase I clinical studies with process validation to support path to commercial approval
- Readily available stock to support your drug conjugation projects and accelerate your development timelines

#### Added value

- Reduce development costs
- · Decrease supply chain complexity
- Limit the risks associated with complex, multi-step reactions

# **Avoid Complex Synthetic Routes**

ADCore products are advanced GMP intermediates that help accelerate drug development efforts by reducing the number of development and manufacturing steps needed to produce Dolastatin, PBD, or Maytansinoid payloads.



#### **DOLCore™ Intermediate**

#### Synthesize dolastatin payloads faster and with less risk

Dolastatins have demonstrated both clinical and commercial success as payloads for ADCs. DOLCore Intermediate is a versatile and advanced intermediate that can simplify the synthesis of dolastatin-10 payloads by reducing the number of synthesis steps from 15-20 to four or fewer.

- Get market exclusivity at least 12-months sooner
- 5 g samples available free of charge
- HPLC Purity ≥ 98%

# **PBDCore™ Intermediate**

#### Develop diverse and highly potent PBDs

Pyrrolobenzodiazepines (PBDs) are an up-and-coming class of payloads, with the first commercial PBD-based ADC launched in 2021. PBDCore™ Intermediate contains the active structural components and handles of PBDs, giving our customers the flexibility to make most PBD payloads.

- 10 g samples available free of charge
- HPLC Purity ≥ 95%

#### **MAYCore™ Intermediate**

#### Simplify maytansinoid payload synthesis

Maytansinoids comprise the second largest ADC payload class in the market. MAYCore™ Intermediate is an advanced intermediate that simplifies maytansine payload synthesis.

- Rapid synthesis of maytansinoid payloads
- 3 g samples available free of charge
- HPLC Purity ≥ 95%

#### **Related Products and Services:**

- DM1 Mertansine
- ADC Express<sup>™</sup> Services
- ChetoSensar<sup>™</sup> Platform

# **Comprehensive Solutions for Your ADC**

We offer comprehensive supply chain reliability from discovery to commercialization of your ADC.

This includes coordinated and collaborative services for the development, manufacturing, and testing of bulk drug substance and drug product. We offer a full range of services to support your ADC projects:

- mAb, linker, payload, conjugation development, and manufacturing services
- Analytical method development and validation
- · Technology transfer and manufacturing
- Stability studies for bulk drug substance and drug product
- Regulatory support

# Payload and Linker Manufacturing Capabilities

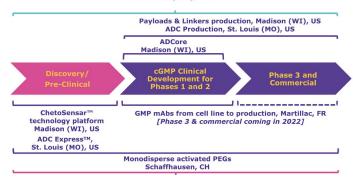
We have more than 30 years of experience working with highly-active and complex molecules. Our Madison, Wisconsin, facility in the United States has a variety of manufacturing spaces and equipment to provide the necessary flexibility for multi-step synthesis of complex and highly potent APIs (HPAPIs) and linker-payloads including the opening of the world's largest single nanogram OEL containment facility in May 2022.

# **Manufacturing Capabilities**

QTY	Equipment	Capacity	Temp Range
7	HPAPI Kilo Labs: Single ng OEL containment	g to kg scale	-75 to +190 °C
6	HPAPI Kilo Labs: Containment down to 30 ng/m³	g to kg scale	-75 to +190 °C
4	Potent Kilo Labs: Containment down to 1 µg/m³	g to kg scale	-75 to +190 °C
3	HPAPI Pilot Plants: Containment down to 30 ng/m³	120–800 L 3–25 kg batch	-20 to +180 °C
2	Potent Production Plants: Containment down to 1 µg/m³	2000 –4000 L 50–400 kg batch	-80 to +180 °C
	Column Chromatography	up to 40 kg silica	

# **ADC Contract Manufacturing Footprint**

Analytical Testing and Product Characterization Rockville (MD), US



Successful use and scale-up of single use technology

#### **ChetoSensar™ Platform**

A technology that solves many challenges with antibody-drug conjugates

- Increased ADC solubility, particularly for higher DAR ADCs
- Wider therapeutic index and higher drug efficacy
- Improved bioconjugation efficiency

# **ADC Express™ Services**

Pre-clinical conjugation services for the best candidate selection

- Mini-prep scale: 10-20 mg ADC construct ± column purification
- Medium-prep scale: up to 100 mg ADC ± column purification
- · Certificate of testing with key quality attributes

### **DM1 - Mertansine**

A GMP quality payload for your drug-conjugate programs

- · Samples available free of charge
- Validated analytical methods
- Free licensing and no royalty payments

For additional information, please visit sigmaaldrich.com/services/contract-manufacturing/high-potent-apis

To place an order or receive technical assistance, please visit sigmaaldrich.com/services/contact-safc

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