



ADCelerate

Rapid, Integrated ADC to IND

ADCelerate is Piramal Pharma Solutions’ rapid approach to delivering Phase-I appropriate ADC drug substance and drug product, so that you can accelerate the delivery of your product to patients in the clinic. *From project initiation to GMP drug product in as little as 12 months, with no compromising on quality.*

Deliverables:

- Fully developed manufacturing processes for ADC drug substance and lyo drug product
- Fully qualified (Phase-I appropriate) analytical methods to support batch release and stability studies (drug substance and drug product)
- Initial stability data on drug substance (6 months) and drug product (1 month)

Material release dates:

Material	Estimated release-to-client time*
Non-GMP Tox Batch DS	7 months
GMP Batch DS	10 months
Non-GMP Pilot Batch DP	11 months
GMP Batch DP	12 months

* Time from project initiation

What we need from you:

- Confirmation of all batch sizes before project initiation
- Confirmation of bioassay protocols and cell lines (CL ≤ 2) before project initiation
- Extinction coefficients for both linker-payload and mAb
- Drug substance specification
- mAb and linker-payload to enable work to begin

Material requirements:

Stage	ADC DS	mAb	Payload-Linker
Initial Analytical Development	~25 mL	-	-
DS Process Development	-	~10g	~1g
DS Small-scale Batches	-	~5% of GMP scale	~5% of GMP scale
Non-GMP Tox Batch DS	-	≤ 200g	≤ 20g
GMP Batch DS	-	tbd	tbd
DP Process Development	~40g ^{a, b}	-	-
GMP Batch DP	tbd ^a	-	-

^a DS material supplied from small-scale, tox or GMP DS batches.

^b DS material requirement will be lower if frozen liquid fill is chosen instead of lyo fill.

Assumptions:

- Standard Piramal Pharma Solutions process used
- TFF purification under standard conditions
- Qualification of analytical methods will be performed to be Phase-I appropriate
- Piramal Pharma Solutions standard document templates used
- Client review of reports but not protocols. Protocol templates to be shared at outset for agreement
- Client review of batch records after disposition

Cost:

Speak to our experienced technical and sales team for an estimate of our competitive pricing.

BusinessOperations.Grangemouth@Piramal.com

If your process or methods are different from this, don't worry!
 Our experienced technical team is happy to discuss how we can make it work for you.

piramalphasolutions.com