

A Novel Long-acting Injectable Formulation

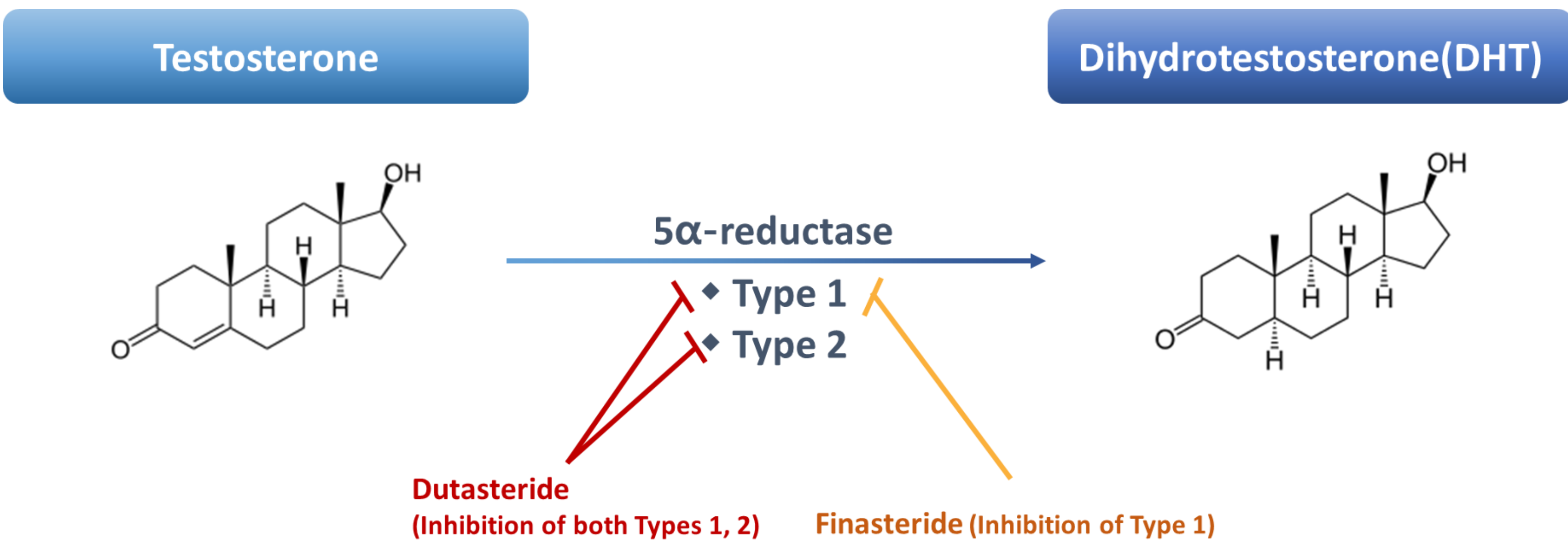
Enabling Sustained Release of Dutasteride over 3 months

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Introduction

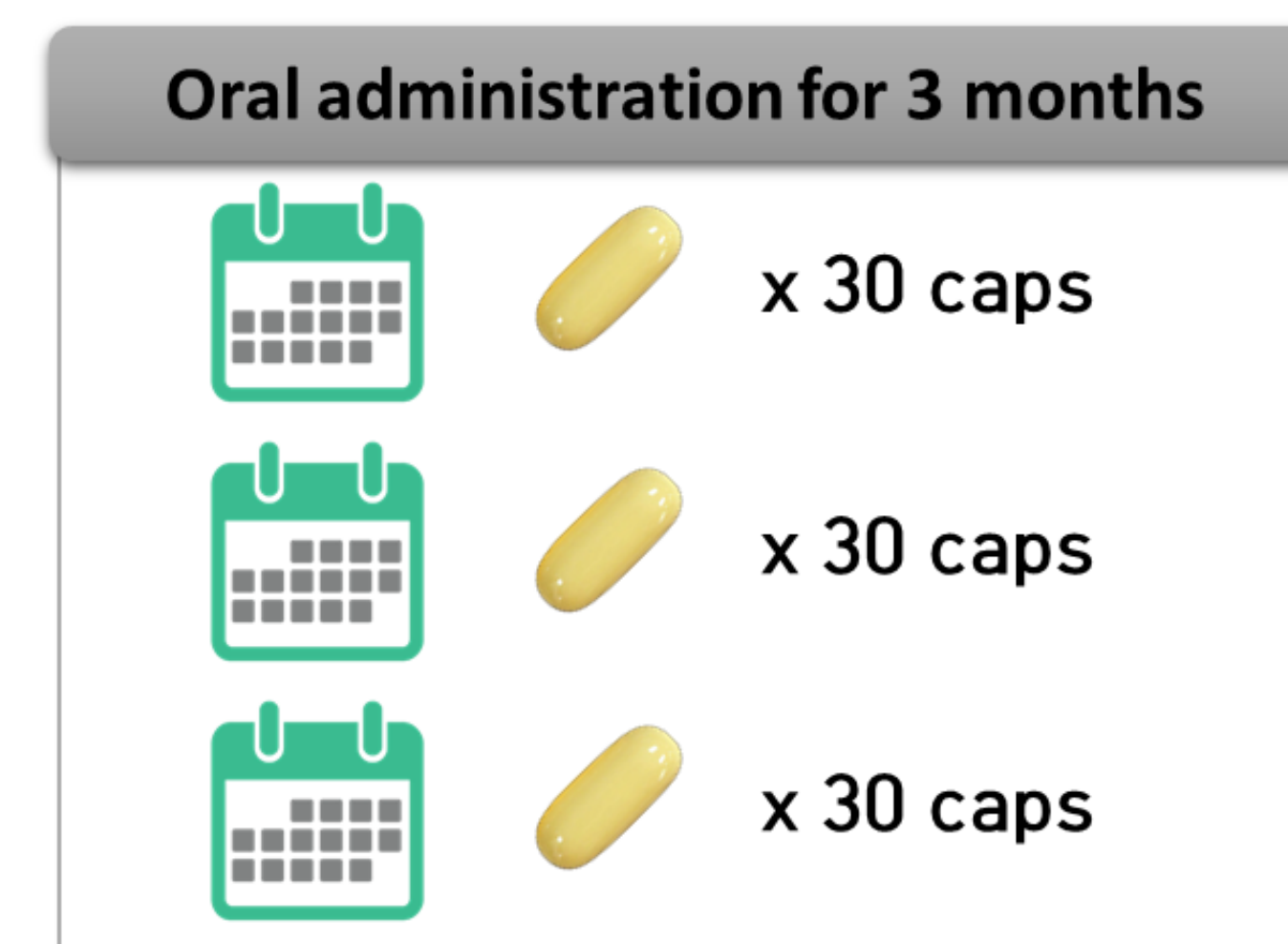
➤ Dutasteride belongs to 5 α -reductase inhibitors



- **Dutasteride** and finasteride, which are both 5 α -reductase inhibitors, used to treat **alopecia and benign prostatic hyperplasia (BPH)** by blocking the conversion of testosterone to dihydrotestosterone (DHT).
- While finasteride selectively inhibits the type 2 isoform of 5 α -reductase, **dutasteride inhibits both the type 1 and type 2 isoforms.**
- Dutasteride is considered to be more effective at lower doses than finasteride in the treatment of androgenic alopecia.

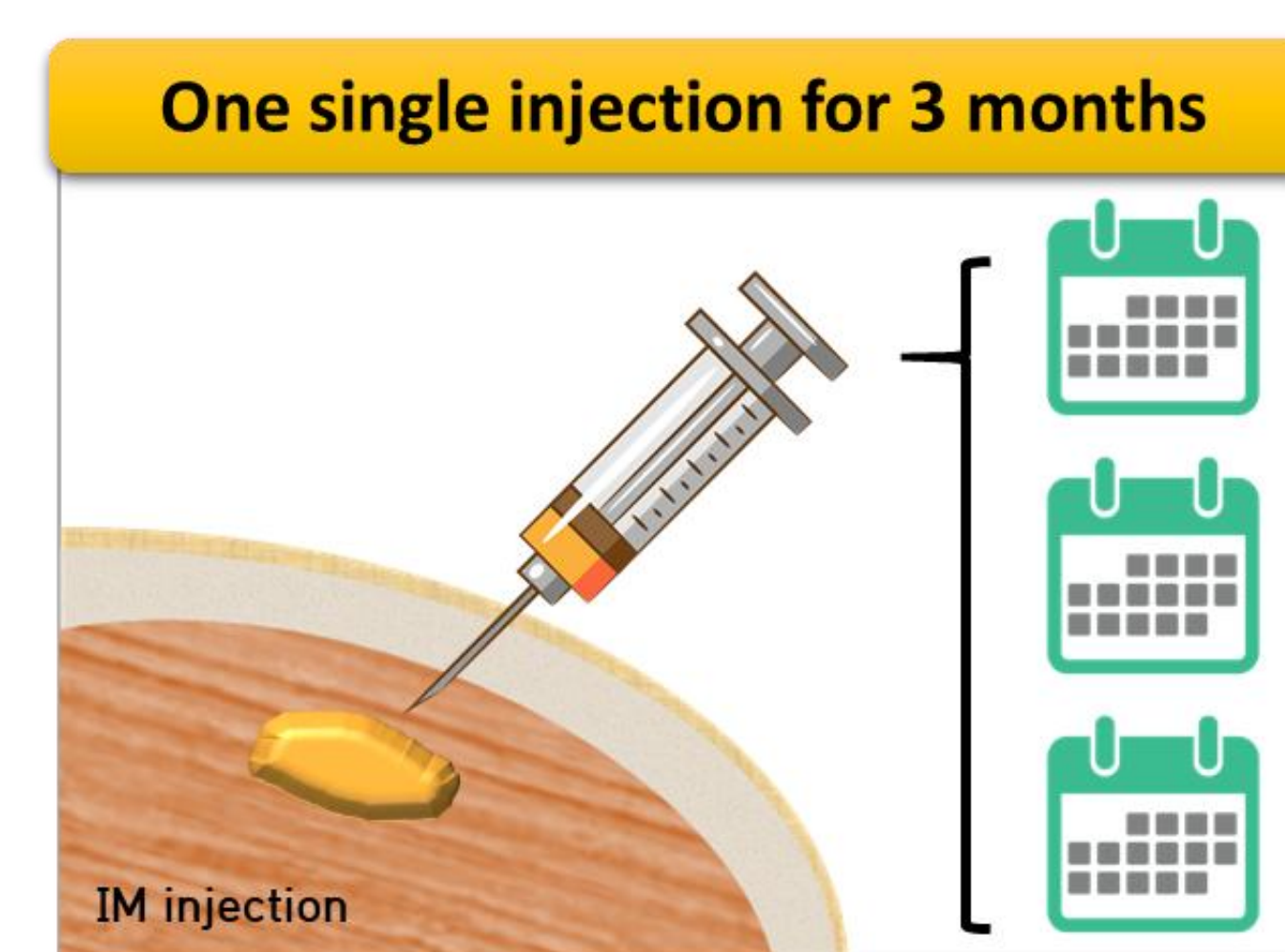
➤ The need for a long-acting injectable system in the treatment of alopecia and BPH

- Long-term daily treatment of alopecia and BPH often results in decreased patient compliance.
- Pregnant women should avoid handling capsules due to skin absorption risks (Teratogenicity).



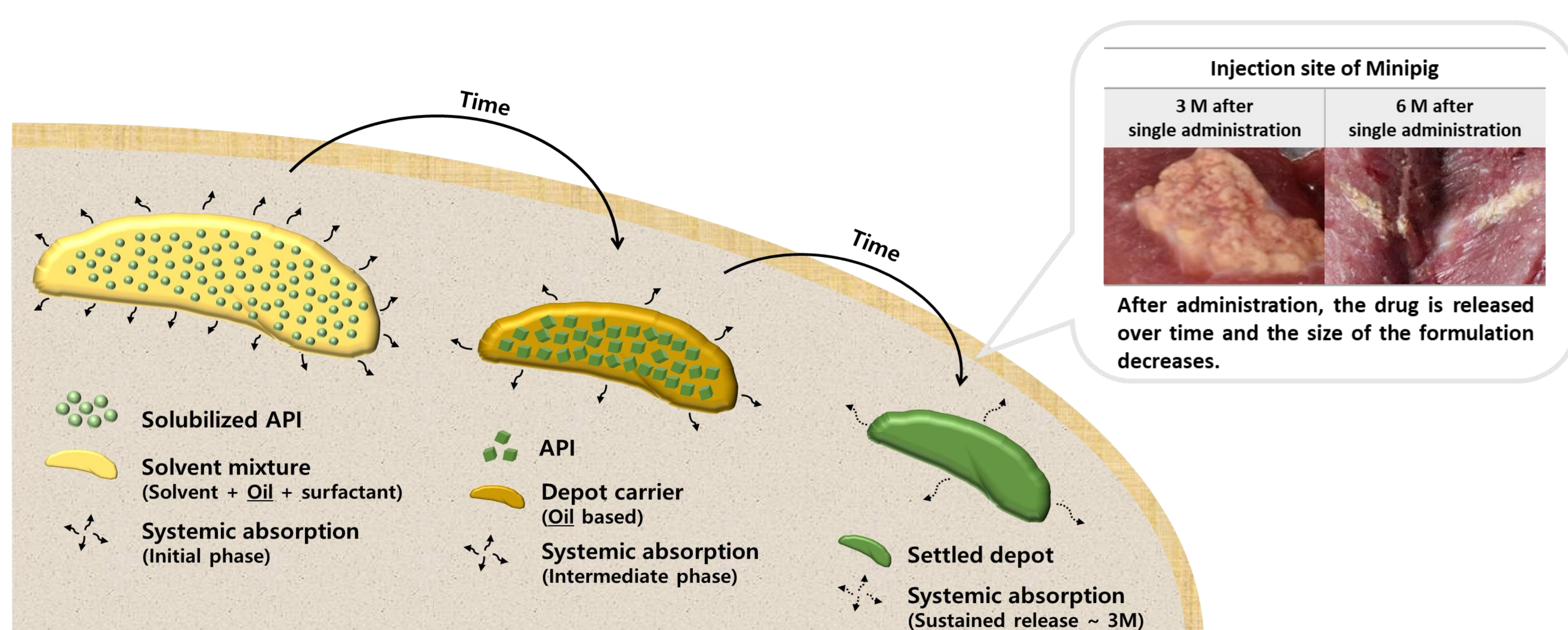
➤ Novel long-acting injectable formulation (CKD-843)

- Designed a **novel long-acting injectable formulation** containing lipid
- **Enhancing the convenience of medication intake** with novel sustained-release technology

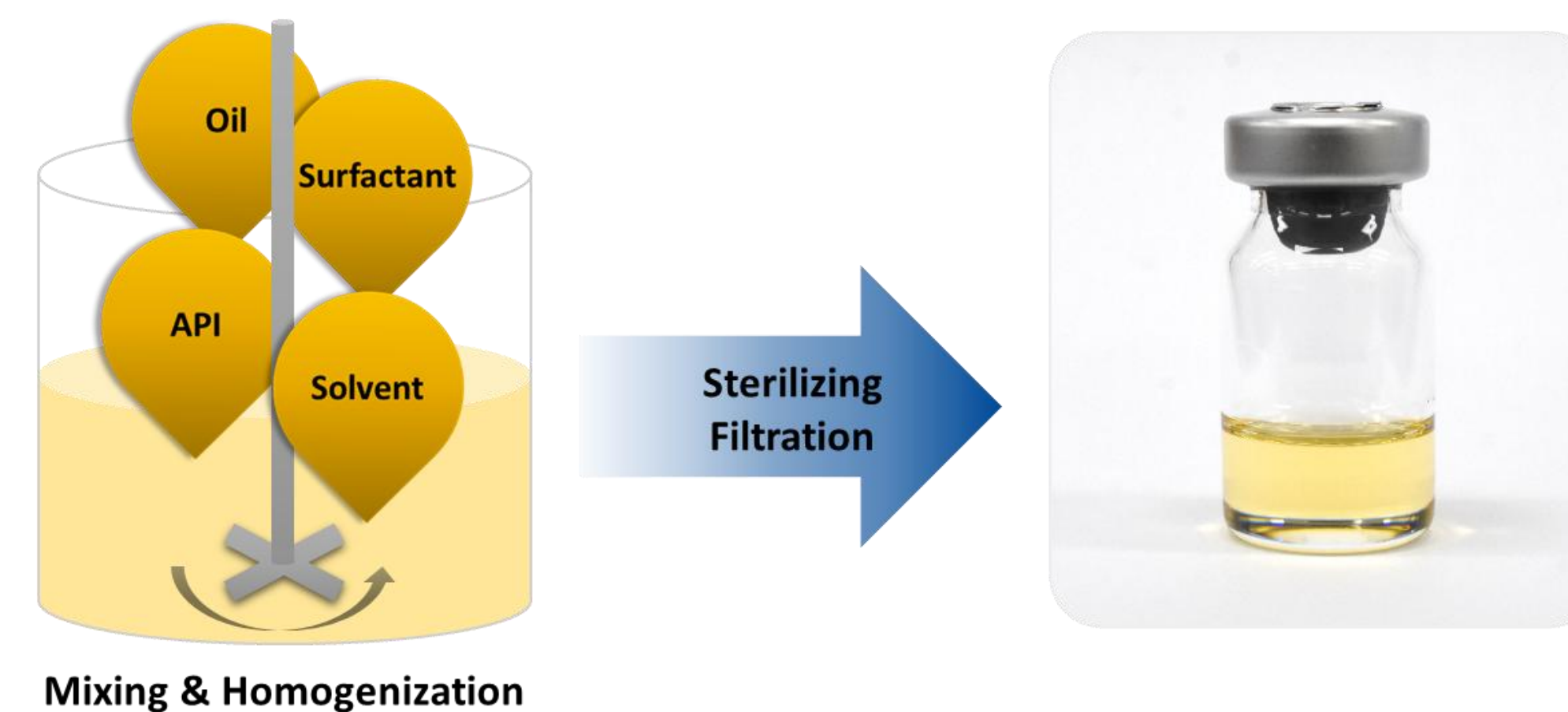


Technical Features of CKD-843

➤ Mechanism of sustained drug release in CKD-843



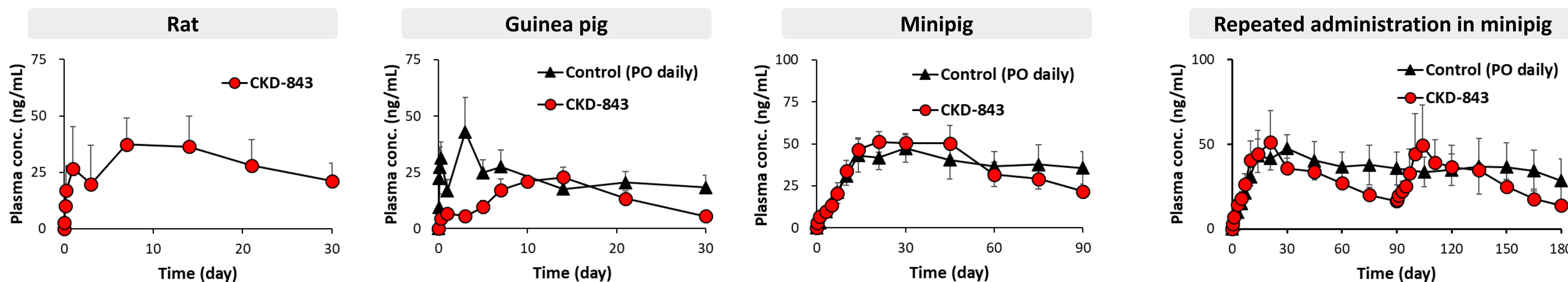
➤ Manufacturing process of CKD-843



- **Simple mixing and dissolving process** using injectable and safe additives
- Low viscosity after manufacturing allows for **smooth filtration and filling processes.**

Results

➤ Pharmacokinetics data of CKD-843 in various species



- Sustained release properties of CKD-843 was confirmed in various species
- In minipigs, the PK profiles of CKD-843 following both single and repeated administration were comparable to those observed in the oral administration group (control).

Conclusion

- We invented a **novel lipid based long-acting injectable formulation (CKD-843)**, which enables **sustained release of dutasteride for more than 3 months without local irritation and initial burst after injection.**
- In preclinical studies, **sustained drug release over 3 months was confirmed in various species.**
- **The PK profiles following both single and repeated administrations of CKD-843** were comparable to those of reference drug, which was administered orally once daily.