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*Vascular endothelial growth factor A (VEGF-A) (AZD-8601)*

*Last program update: August 5, 2020*
Vascular endothelial growth factor (VEGF-A) overview

- VEGF-A is a potent angiogenic factor that promotes growth of blood vessels.
- Preclinical data suggests that expression of this growth factor in the ischemic heart could increase blood flow and partially restore cardiac function.
- Coronary artery disease, the primary cause of ischemic heart failure, affects the arteries providing blood supply to the cardiac muscle.
- In 2015, coronary artery disease resulted in 366,000 deaths in the United States, and 8.9 million deaths globally.

Moderna concept: Locally-administered mRNA encoding VEGF-A to promote recovery of cardiac function through partial tissue regeneration.
VEGF-A (AZD8601)

**Phase 1 successful, Phase 2 ongoing**

### Phase 1

**Intradermal injection, mRNA vs. placebo, in diabetic patients**

### Phase 2

**Intracardiac injection, mRNA vs. placebo, in patients undergoing CABG**

- **Blood Flow**
  - Normal
  - Impaired

![Intradermal injection image](image1.png)

![Intracardiac injection image](image2.png)
VEGF-A (AZD8601)

Phase 1 first-in-human study demonstrated safety and tolerability

Safety and tolerability monitoring procedure:

- Adverse events were monitored from screening and during the 6-month follow-up period
- Vital signs (pulse and blood pressure), electrocardiography, physical examinations, and laboratory assessments (hematology, blood biochemistry, coagulation, urinalysis, viral serology, and urine drug and alcohol tests)
- Local reactions at injection sites: redness, bruising, swelling, itching and pain

Safety results and conclusions:

- No adverse events leading to discontinuation occurred
- The only causally treatment-related adverse events were injection-site reactions (all mild), occurring in all but one participant receiving VEGF-A mRNA. These local reactions were attributable to VEGF-A-mediated vasodilation, supporting further clinical investigation of VEGF-A mRNA as an angiogenic therapy
- Minor changes from baseline in laboratory parameters or vital signs were noted but none of these was considered clinically relevant
VEGF-A (AZD8601) Phase 1a data

Intradermal AZD8601 gives rise to dose-dependent production of VEGF-A protein

- Phase 1a microdialysis sampling of VEGF-A protein in diabetic patients
- Proof of mechanism fulfilled following a single intradermal injection of AZD8601

Intradermal delivery of modified mRNA encoding VEGF-A in patients with type 2 diabetes

Li-Ming Gan1,2,3, Maria Lagerström-Ferme1, Leif G. Carlsson1, Cecilia Arvidsson1, Anna-Charlotte Egner1, Ann-Rita Rudni2, Magnus Käer1, Anna Callies2, James D. Thompson2, John Joyce2, Liqiu Chilada3, Thomas Koernickel3, Recess Furu1, Kenneth R. Chien2,5 & Regina Fritsche-Danilo1
VEGF-A (AZD8601) Phase 1b data

**Single dose of intradermal VEGF-A mRNA acutely restored baseline skin blood flow**

**Phase 1b laser scanning microscopy of injection sites in diabetic patients**

**Acute improvement in skin blood flow**

- VEGF-A mRNA 360 µg (6 sites; n = 6)
- VEGF-A mRNA 72 µg (6 sites; n = 6)
- VEGF-A mRNA 24 µg (6 sites; n = 6)
- Placebo (n = 27)

Intradermal delivery of modified mRNA encoding VEGF-A in patients with type 2 diabetes

- U-Ming Gao
- Maria Lagerström-Ferm
- Leif G. Carlsson
- Cecilie Arvidsson
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- Kenneth B. Chen
- Regina Fritsche-Danhauer

*moderna*
VEGF-A (AZD8601) Phase 2a to evaluate safety and activity on blood flow in a heterogeneous CABG population

O^{15}-PET imaging is used to create tailored injection maps in patients

Injection sites in areas with impaired blood flow
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