From: [redacted][JPPBE]
To: [redacted][JPPBE]
Subject: J&J single-dose COVID vaccine submission to European Medicines Agency (EMA)
Date: jeudi 18 février 2021 19:24:28
Attachments: image005.jpg
image002.png
image004.png

Update on our COVID-19 Vaccine Program

Submission of European Conditional Marketing Authorisation Application

Esteemed Commissioner,

Johnson & Johnson announced this week that Janssen-Cilag International N.V. has submitted a **conditional Marketing Authorisation Application (cMAA) to the European Medicines Agency (EMA)** seeking authorisation for its investigational **single-dose Janssen COVID-19 vaccine candidate**.

The submission is based on topline efficacy and safety data from the Phase 3 ENSEMBLE clinical trial. The trial, **conducted in eight countries across three continents**, includes a **diverse and broad population.**

If authorized, Janssen's investigational single-dose vaccine is estimated to remain stable for two years at -20°C, at least three months of which **can be stored in most standard refrigerators** at temperatures of 2°-8°C.

Full details on this announcement can be found in the EMA press release.

Sincerely,

[redacted]
Global Supply Chain, Johnson & Johnson

[redacted]