ANIKA
THERAPEUTICS

Abano Terme, January 14, 2013

European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Dr. Tomas Salmonson
Chair, Committee for Medicinal Products for Human Use

Dr. Christian Schneider
Chair, Committee for Advanced Therapies

Subject: Withdrawal of Hyalograft C autograft, (characterized viable autologous chondrocytes expanded in vitro, seeded and cultured on a hyaluronan-based scaffold), 4 million cells seeded on scaffold, for implantation. **EMEA/H/C/002657**

Dear Sirs,

I would like to inform you that, at this point of time, Anika Therapeutics S.r.l. has made the decision to withdraw the application for Marketing Authorisation of Hyalograft C autograft, (characterized viable autologous chondrocytes expanded in vitro, seeded and cultured on a hyaluronan-based scaffold), 4 million cells seeded on scaffold, for implantation, which was intended to be used for the surgical repair of symptomatic cartilage defects of the femoral condyle (medial, lateral) or trochlea, caused by acute or repetitive trauma (Outerbridge Grade III-IV) in adults.

This withdrawal is made for the following reasons:

- The CAT's preliminary assessment on the data provided thus far does not allow the Committee to make the conclusion that a positive benefit risk balance exists.
- There are no ongoing clinical trials or compassionate use programmes for this medicinal product in Europe.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree that this letter o be published on the EMA website.

Yours sincerely,

[redacted]

Anika Therapeutics S.r.l.

[redacted]