SUMMARY OF THE CLINICAL INVESTIGATION PLAN # 21E0805

ANSM registration #:	**2021-A02728-33**
Clinical investigation plan #:	**21E0805**
Title of the clinical investigation:	**CLINICAL STUDY FOR THE EFFECTIVENESS OF USE OF AN INJECTABLE MEDICAL DEVICE GANA X® IN THE TREATMENT OF BUTTOCKS VOLUME DEPRESSION**
Sponsor:	**GCS Co., Ltd.** 1008 Ho, Sunil Technopia Bldg, 555 Dunchon-daero Jungwon-gu, Seongnam-si, Gyeonggi-do KOREA
Development phase	Post market study Interventional Device used according to Instruction For Use (IFU)
Objectives:	The primary objective is to evaluate the effectiveness of Gana X® in improving buttocks volume 6 months after treatment. The secondary objectives of the study are: - to evaluate the effectiveness of Gana X® in improving buttocks volume $1^{1/2}$, 9, 12, 18 and 24 months after treatment. - to evaluate the effectiveness of Gana X® on the global aesthetic improvement of buttocks $1^{1/2}$, 6, 9, 12, 18, 24 months after treatment as rated by the evaluator. - to evaluate the effectiveness of Gana X® on the global aesthetic improvement of buttocks $1^{1/2}$, 6, 9 12, 18, 24 months after treatment as rated by the subjects. - To evaluate the subject satisfaction with Gana X® $1^{1/2}$, 6, 9, 12, 18 and 24 months after treatment. - To evaluate the injector satisfaction with Gana X® after initial and touch-up injection if applicable. - To evaluate the safety of Gana X®.
Design:	The study will be: • In open, • Single center.
Planned Sample Size:	55 subjects included.
Number of investigational study sites:	1 site (France).
Inclusion criteria:	1. Healthy Subject. 2. Sex: male or female. 3. Age: between 18 and 65 years. 4. Subject with mild to moderate buttock volume depression and/or seeking buttocks volume augmentation based on investigator evaluation. 5. Subject wiling to abstain from other body contouring procedures during the whole study period. 6. Subject psychologically able to understand the study related information and to give a written informed consent. 7. Subject having given freely and expressly his/her informed consent. 8. Subject willing to have photographs taken.

	9. Subject affiliated to a health social security system. 10. Female of childbearing potential should use a contraceptive regimen recognized as effective since at least 12 weeks before screening visit and during the whole study period.
Exclusion criteria:	1. Pregnant or nursing woman or having given birth within the last year or planning a pregnancy during the study. 2. Excessive subcutaneous fat in the area to be treated. 3. Excessive skin laxity on the area to be treated. 4. Severe buttocks ptosis. 5. Subject who had been deprived of their freedom by administrative or legal decision or who is under guardianship. 6. Subject in a social or sanitary establishment 7. Subject participation to another research on human beings or who is in an exclusion period of one. 8. Subject having already received 4500 euros indemnities for participation in research involving human beings in the 12 previous months or exceeding these 4500 euros with his participation in the present study. 9. Subject suspected to be non-compliant according to the investigator's judgment. 10. Subject suffering from a severe or progressive disease or any other pathology that may interfere with the evaluation of the study results. 11. Subject with known history of or suffering from autoimmune disease and/or immune deficiency. 12. Subject with a history of cellulitis, streptococcal disease, such as acute rheumatic fever or recurrent sore throats and in case of acute rheumatic fever with heart complications. 13. Subject suffering from inflammatory and/or infectious cutaneous disorders in or near the studied zones (e.g. acne, chronic eczema, atopic dermatitis…). 14. Subject with an abscess, unhealed wound, or a cancerous or precancerous lesion on the studied zone. 15. Subject prone to develop inflammatory skin conditions or having tendency to bleeding disorders. 16. Subject with a tendency to develop keloids or hypertrophic scarring. 17. Subject with significant scarring, open wounds, lesions or tattoos in or near the area to be treated. 18. Subject having history of allergy or anaphylactic shock including hypersensitivity to Poly-l-lactic acid, to lidocaine or to one of the components of the tested devices or antiseptic solution. 19. Subject having received a dose of COVID-19 vaccine within the 14 days prior to injection visits or planning to receive a dose in the 14 days following injections. 20. Subject having received treatment on or near the buttocks (laser, dermabrasion, surgery, radiofrequency, cryolipolysis, buttocks electrostimulation, endermologie, liposuction, other energy-based treatment, surgery…) within the 12 months prior to screening visit. 21. Subject having received injection with a resorbable filling product in or near the buttocks within the 12 months prior to screening visit. 22. Subject having received at any time the following treatments in the area to be treated: • Buttocks implants;

	• Buttocks fillers (e.g., silicone, semi-permanent or permanent fillers or autologous fat injections); • Injections for the treatment of cellulitis. 23. Subject having started or changed her oral contraceptive or any other hormonal treatment during 12 weeks prior to screening visit. 24. Subject using medication such as aspirin, nonsteroidal anti-inflammatory drugs (NSAID) (ibuprofen, naproxen, …), antiplatelet agents, anticoagulants or other substances known to prolong bleeding time within 1 week prior to injection visits. 25. Subject undergoing a topical treatment on the test area or a systemic treatment: • Antihistamines during the 2 weeks prior to injections visits (D0 and touch-up visit). • Immunosuppressors and/or corticoids during the 4 weeks prior to injections visits (D0 and touch-up visit). • Retinoids during the 6 months prior to injections visits (D0 and touch-up visit). 26. Intensive exposure to sunlight or UV-rays within the month before injection visits and one month after. 27. Subject planning to loss or gain weight for the duration of the study. 28. Subject planning to change her/his life habits during the study.
Investigational device: **Name / code** **Classification** **Ingredient** **Galenic form** **Administration route**	 Gana X® Class III medical device Poly-L-Lactic Acid (630mg), Sodium Carboxymethyl Cellulose, Mannitol. Sterile freeze-dried preparation (powder) Injection in the deep dermis and subcutaneous layer.
Endpoints:	<u>Primary effectiveness endpoint:</u> Mean change in buttocks volume from baseline to 6 months after treatment using fringe projection system. <u>Secondary effectiveness endpoints:</u> - Mean change in buttocks volume from baseline to $1^{1/2}$, 9, 12, 18 and 24 months after treatment using fringe projection system. - GAIS responder rates $1^{1/2}$, 6, 9, 12, 18 and 24 months after treatment as assessed by an independent live evaluator. A responder is defined as a subject having “Improved”, “Much improved” or “Very much improved” score according to GAIS. - GAIS responder rates $1^{1/2}$, 6, 9, 12, 18 and 24 months after treatment as assessed by the subjects. - Proportion of satisfied subjects $1^{1/2}$, 6, 9, 12, 18 and 24 months after treatment using a questionnaire. - Injector’s satisfaction regarding injection quality after initial and touch-up injection using a questionnaire. <u>Secondary safety endpoints:</u> Investigational device safety will be assessed by collection of Injection Site Reactions (ISRs) and Adverse Events (AEs) throughout

	the study by the investigator. Subjects will record ISRs and AEs in their subject diaries.
Study Procedures:	A screening visit will allow to inform and preselect the subjects. On D0, fringe projection acquisitions and photographs will be done before injection. Eligible subjects will receive a first injection of the investigational device. Immediately after injection, injector's treatment satisfaction will be collected. Investigator evaluator will collect AEs and ISRs immediately after injection. A month and a half after initial injection ($M1^{1/2}$), GAIS scoring, fringe projection acquisitions and photographs will be done before touch-up injection (if applicable). A touch-up injection will be made if necessary, according to injector and subject opinion. Investigator evaluator will collect AEs and ISRs before and after touch-up if applicable. Subject's treatment satisfaction and injector's treatment satisfaction (if applicable) will be collected. Six (M6), nine (M9), twelve (M12), eighteen (M18) and twenty-four (M24) months after initial injection, effectiveness scoring (GAIS scale), fringe projection acquisitions and photographs will be done. Subject's treatment satisfaction will be collected. Investigator evaluator will collect AEs and ISRs
Statistical methods:	**<u>For the primary evaluation criterion:</u>** The primary endpoint is the mean change in buttocks volume from baseline to 6 months after treatment using fringe projection system. Descriptive statistics for quantitative data (N, mean, standard deviation, minimum and maximum) will be presented at D0 before injection and M6. **<u>Inferential analysis:</u>** A Wilcoxon signed rank test, or a paired t test will be applied to evaluate the change from baseline (D0 before injection) to M6. The normality assumption will be tested using a Shapiro Wilk test (α=0.01). The bilateral approach will be used. **<u>For the secondary evaluation criteria:</u>** All the variables will be described using adapted statistics according to their type (quantitative data or qualitative data). For quantitative data a Wilcoxon or paired t test will be applied to assess the change from baseline. The bilateral approach will be used with a significance level of 0.05.
Foreseen study duration:	Clinical investigation beginning: Q1 2022 Clinical investigation end: Q3 2024 Inclusion duration: Maximum 6 months Clinical investigation global duration: 30 months Duration by subject: 24 months + screening period

FLOW-CHART

Procedure	**Visit 1 Screening**	**Visit 2 Day 0**	**Visit 3 M1[1/2]**	**Visit 4 M6**	**Visit 5 M9**	**Visit 6 M12**	**Visit 7 M18**	**Visit 8 M24**
Days	D-X	D0	D40 ± 2	D160 ± 4	D270 ±4	D365 ± 7	D540 ± 14	D730 ± 14
Informed consent form signature	●							
Medical examination	●							
Medical history and previous and concomitant treatments collection	●							
Checking of the inclusion and exclusion criteria	●							
Pregnancy test		●[b]	●[b]					
Confirmation of eligibility		●[b]						
Photographs		●[b]	●[b]	●	●	●	●	●
Fringe projection acquisitions (2 areas)		●[b]	●[b]	●	●	●	●	●
Injection + anaesthesia (if necessary)		●	●Touch up					
GAIS live assessment by an independent evaluator			●[b]	●	●	●	●	●
GAIS assessment by the subjects			●[b]	●	●	●	●	●
Subjective evaluation questionnaire for subjects			●[b]	●	●	●	●	●
ISR live assessment by an independent evaluator		●[a]	●[b+a]	●	●	●	●	●
ISR assessment by the subjects		Completed each day during 4 weeks after injection at home by the subject.						
Subjective evaluation questionnaire for injector		●[a]	●[a]					
AE and concomitant treatments and procedures collection	●	●	●	●	●	●	●	●
Study end								●

Keys: [b]: Before injection; [a]: After injection