Interest & Feasibility Questionnaire

HYMN: A randomised controlled trial comparing hyperthermia plus mitomycin to a second course of bacillus Calmette-Guérin or institutional standard of care in patients with recurrence of non-muscle invasive bladder cancer following BCG induction and maintenance.

Many thanks for your interest in this Phase III trial. Please review the trial synopsis and discuss the questions below with your colleagues and complete this form accordingly.

Please insert the Investigators name and details (ideally this should be the intended Principal Investigator)

Name:

Institution:

Address:

Tel:

Fax:

E-mail:

Please can you indicate your experience of clinical trials below:-

1. Do you have previous clinical trials experience? ☐Yes ☐ No

2. How many have you been the Principal Investigator for?

Please can you indicate the number of eligible patients at your centre below :-

1. Please state the current number of patients with recurrence of non-muscle invasive bladder cancer following BCG that you see **each year** in your institution: *a year*

2. Please provide a realistic estimate of how many patients, from your institution, you can enrol in this trial on a **yearly basis** (*please see trial eligibility criteria*) *a year*

3. Do you currently and/or in the near future have any competitive clinical trials in the same patient population?

☐Yes

☐ No

If yes, when is enrolment expected to end

Please can you indicate your centres resources below :-

1. Is there a research nurse(s) attached to the trial team? ☐Yes ☐ No

2. Do you currently operate the Synergo Hyperthermia system in your centre? ☐Yes ☐ No

3. Would you be willing to accept a Synergo Hyperthermia system for this trial? ☐Yes ☐ No

4. In this trial, your centre is required to perform a cystoscopy every 3 months for years one and two of follow-up. Patients will be followed according to local guidance subsequently, although 3-monthly surveillance is recommended for year 3, followed by 6-monthly or annual follow-up thereafter.

   Are the number of cystoscopies proposed routine at your centre? ☐Yes ☐ No

   If no, please specify your centres practice below

5. The first 3 month cystoscopy will be a rigid cystoscopy performed under general or regional anaesthesia. Subsequent cystoscopies will be by flexible or rigid cystoscopy

   Would this hinder your participation in this study? ☐Yes ☐ No

   If yes, please specify below

Institutional standard for failed BCG Maintinence:-

1. What therapy do you administer to patients who have a recurrence of non-muscle invasive bladder cancer following maintenance BCG and are not fit or not willing to undergo for cystectomy? (assume prior intravesical mitomycin therapy)

EMDA mitomycin ☐Yes ☐ No
Intravesical epirubicin ☐Yes ☐ No
Intravesical gemcitabine ☐Yes ☐ No
Interferone plus BCG ☐Yes ☐ No
Other. If yes please specify below ☐Yes ☐No

THANK YOU FOR YOUR FEEDBACK

Please return via email or fax to:

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