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SCREENING DATA SUMMARY  
 DEVELOPMENTAL THERAPEUTICS PROGRAM  
 DIVISION OF CANCER TREATMENT  
 NATIONAL CANCER INSTITUTE, BETHESDA, MD 20205  
 SYNTHETIC PRODUCTS

31  
 S99 DATE: 83/09/02 NSC 999999  
 PAGE 14  
 1ST SCR S.I. R.C./DATE PUB  
 \*\*

ACQ M.C./DATE QNS OTHER  
 7A 790617

29  
 -----CONTINUED-----  
 3LE31 TIS:1 LVL:5 RT:1 TRTMT SCHED: Q01DX05 DAY 1ST INJ= 1 TOTAL INJ= 15

24 25 26 27 28  
 ABOVE SCHED REPEATED ON DAYS : 010,020 28 15 1ST RX TIME = 13:15 HRS 28

SMPL	SCR	EXP #	DATEON	V	FED	TED	TXSUR	DOS/INJ/U	BWD	SOL	C/NT/TS	EVAL	T/CX
9	10	8	11	12	13	17	18	19	20				
ND00	90	12345	830726	02	030	005	WD1/2: 1/ 5	TSC: 22P	SSC: L	SEX: M	CSC: 1		
*	017/04	018/01	019/01	1	KE=	4.43	06/06	200.00	-3.6	1	00 00 00	17.4	207
*	006/01	015/03	017/02	2	E=	2.57	06/06	100.00	-2.4	1	00 00 00	15.3	182
*	013/01	014/03	015/02	3	E=	1.68	05/06	50.00	-2.2	6	30 00 00	14.3	170
*	012/01	013/01	014/04	4	KE=	1.33	06/06	25.00	-1.0	1	00 00 00	13.9	165
*	012/03	014/02		5	KE=	0.09	05/05	12.50	-0.8	1	00 00 00	12.5	148
23	#### COMMENT: ONE ANIMAL MISSING - WEIGHTS ADJUSTED												
*	008/18	009/10	010/01				30/30	CNTRL	HOST: 06	BWC = 2.0		8.4	
23	#### COMMENT: RUN WITH 3LE31-12149												

FOOTNOTE:

Ⓜ MORTALITY IS GIVEN AS DAY/DEATH COUNT (NOT SURVIVORS)

SYN

999999

17

- 1 Blank = Not new this run.  
\* = New this run.  
C = Data modified this run by the DPC.  
R = Packs revised by the Screener (these data affected).  
S = Packs revised by the Screener (these data unaffected).
- 2 Death Pattern Data (DAY/DTHS) – Maximum of 3 entries per line; use multiple lines as necessary.
- 3 Log Cell Kill Reduction.
- 4 Designates data appearing on this and subsequent lines as applicable to Control (CNTRL) Group.
- 5 Host Code for all animals in the experiment (Test and Control).
- 6 BWD = Animal Body Weight Difference which is computed by subtracting the Control Group body weight change from the Test Group body weight change.
- 7 BWC = Body Weight Change calculated as final average body weight minus initial average body weight. This item is calculated for the Control Group only.
- 8 DATEON = Date the experiment was initiated. (YYMMDD)
- 9 SMPL = Compound Sample Number.
- 10 SCR = Screener Code.
- 11 V = Vehicle Code.
- 12 FED = Final Evaluation Day.
- 13 TED = Toxicity Evaluation Day.
- 14 TXSUR = Surviving animals/total animals on Toxicity Evaluation Day.
- 15 DOS/INJ/U Dose amount per injection, normally expressed as mg/kg of animal body weight/injection. Units other than mg/kg/inj are flagged with a "unit" code under the "U".
- 16 C/NT/TS = Cures(C)/No-Takes(NT)/Tumored Survivors (TS) as reported by the Screener.

\*Varies by Test System.

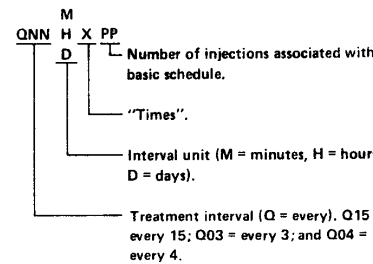
- 17 "WD1:2:1, 5" = This item identifies initial (1) and final (2) animal weigh days. (In this example, the days are 1 and 5.)
- 18 "TSC:22P" = This item identifies the Test Status Code (TSC) and TSC suffix. P – Active Test, F – Inactive Test, or R – Erratic Test (unreliable data).
- 19 "SSC:L" = This item identifies any Special Study Code (SSC) associated with the test. (In this example, the SSC is "L".)
- 20 "CSC:1" = This item identifies the Control Status Code (CSC) associated with the experiment. (In this example, the CSC is "1".)
- 21 EVAL = The calculated value of the Test Group and/or Control Group evaluation based on the test system evaluation parameter.
- 22 T/C % = The test evaluation expressed as a percent of the control evaluation, providing a measure of effectiveness of the compound being tested. Survival systems indicate a degree of success when T/C percents exceed 125.\* Tumor inhibition systems indicate a degree of success when the T/C percents do not exceed 42.\* Minus values (only occurring for tumor inhibition systems) reflect the percent of tumor regression between initial and final tumor volume.
- 23 ##### Comment = Indicates a Screener comment applicable to the data immediately preceding the comment line.
- 24 3 L E 3 1 = Test System used
  - Site of inoculum implant.
  - Parameter of evaluation (i.e., 2 = mean survival time; 3 = median survival time; etc.).
  - Tumor Code (LE = L1210 Leukemia).
  - Animal Host Group (i.e., 3 = mice; 5 = rats; 7 = hamsters).
- 25 TIS:1 = Type of Tumor Inoculum.

- 26 LVL:5 = A one or two position field where the left-most position is a coded representation of the inoculum level and the right-most position (if present) represents a multiplier value.

- 27 RT:1 = Route of Administration for compound (or vehicle) being tested. See pg. 11

- 28 TRTMT SCHED = The treatment schedule followed in administering the compound being tested, taking the form: See pg. 9

Basic Schedule:



DAY 1ST INJ = RR First day basic schedule initiated.

TOTAL INJ = SS Total injections to be administered.

ABOVE SCHED REPEATED ON DAYS:  
TTT, TTT, TTT . . . TTT Each day the basic schedule is to be re-initiated (if appropriate).

1ST RX TIME = 13:15 HRS Time of 1st INJ (if provided in military time (13:15 = 1:15 PM)).

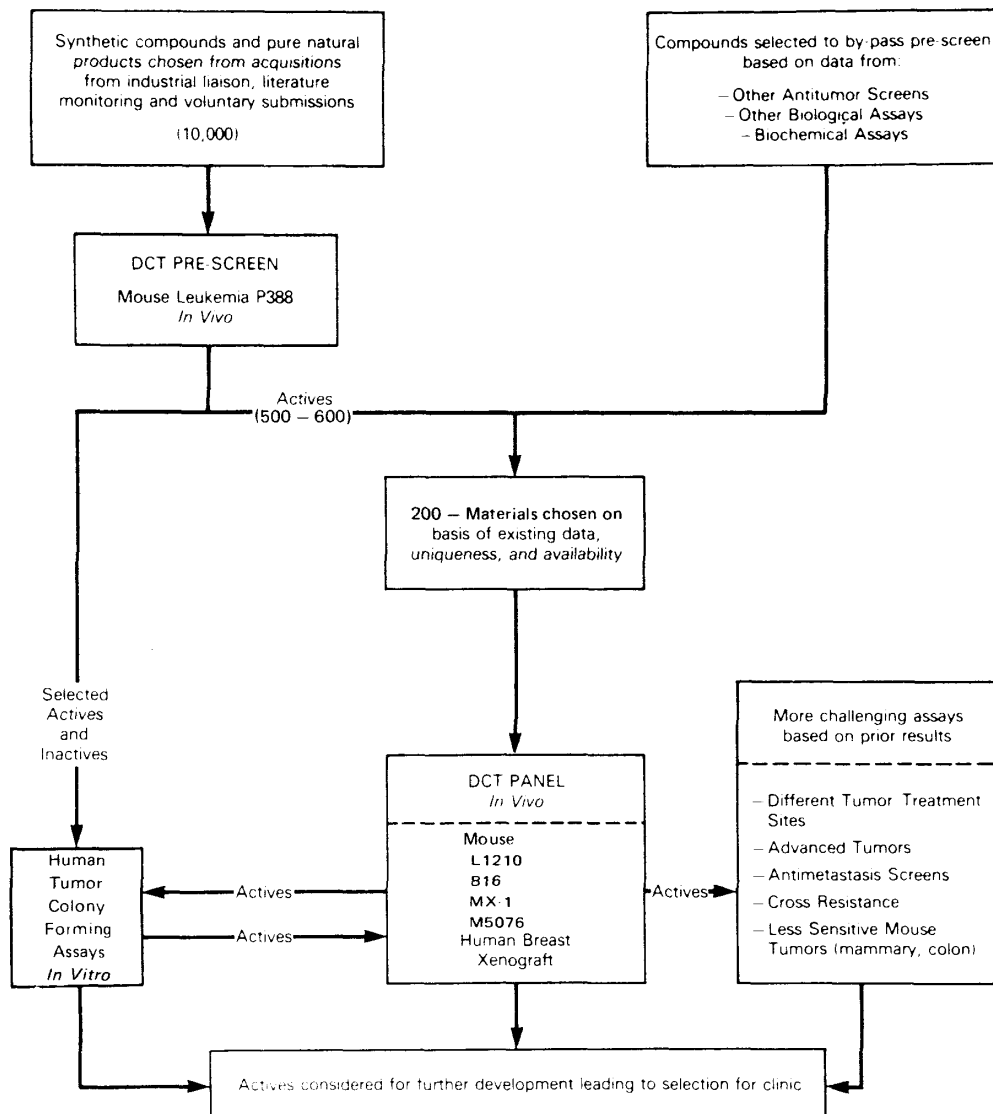
- 29 Same Test System, Tissue, Level, Route, and Treatment Schedule as from Previous Page.

- 30 SOL = Compound Solubility.

- 31 Screener or Supplier number.

80 Column Screening Data Summary Interpretations

### FLOW OF DRUGS THROUGH DCT SCREENS



NOVARTIS EXHIBIT 2045

## ACTIVITY THRESHOLDS OF COMMON SYSTEMS

<u>MODEL</u>	<u>CODE</u>	<u>DRUG RT/SCHED</u>	<u>PARAMETER</u>	<u>ACTIVE T/C%</u>	
				<u>MC1</u>	<u>DN2</u>
<b><u>PRESCREEN</u></b>					
IP P388 LEUKEMIA	3PS31	IP/Q1DX5	MED SURVIVAL TIME CONFIRMING TEST	≥ 127 ≥ 120	≥ 175 ≥ 175
<b><u>TRANSPLANTED MOUSE TUMORS</u></b>					
*IP B16 MELANOMA	3B131	IP/Q1DX9	MED SURVIVAL TIME	≥ 125	≥ 150
SC B16 MELANOMA	3B132	IP/Q1DX9	MED SURVIVAL TIME	≥ 140	≥ 150
SC CD8F1 MAMMARY	3CDJ2	IP/Q1DX1	MED TUMOR WT CHANGE	≤ 20	≤ 0
SC COLON 38	3C872	IP/Q7DX2	MED TUMOR WT	≤ 42	≤ 10
*IP L1210 LEUKEMIA	3LE31	IP/Q1DX9	MED SURVIVAL TIME	≥ 125	≥ 150
*IP M5 SARCOMA	3M531	IP/Q4DX4	MED SURVIVAL TIME	≥ 125	≥ 150
<b><u>HUMAN TUMOR XENOGRAFTS</u></b>					
SRC CX-1 COLON	3C2G5	IP/Q4DX4	MEAN TUMOR WT CHANGE	≤ 20	≤ 10
SC CX-1 COLON	3C2H2	IP/Q4DX3	MEAN TUMOR WT CHANGE	≤ 20	≤ 10
SRC LX-1 LUNG	3LKG5	IP/Q4DX3	MEAN TUMOR WT CHANGE	≤ 20	≤ 10
SC LX-1 LUNG	3LKH2	IP/Q4DX3	MEAN TUMOR WT CHANGE	≤ 20	≤ 10
*SRC MX-1 MAMMARY	3MBG5	IP/Q4DX3	MEAN TUMOR WT CHANGE	≤ 20	≤ 10
SC MX-1 MAMMARY	3MBH2	IP/Q4DX3	MEAN TUMOR WT CHANGE	≤ 20	≤ 10
* DEB TUMOR PANEL					

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